EPA Jacket 33907-2
Volume 1

DB

NOV 9 2001

Dr. Iain Weatherston, Ph.D.
Technology Sciences Group Inc.
4061 North 156th Drive
Goodyear, AZ 85338

Subject: Pending Application EPA #33907-E dated October 5, 2001
Application for Pesticide Registration of Comfort Zone ®

Dear Dr. Weatherston:

All data submitted to the Agency to support registration actions must conform to a standard format, organization, and other requirements described in Pesticide Registration Notice (PRN) 86-5 dated July 29, 1986. This notice was mailed to all registrants on record with the Agency at that time and is currently available on the Internet (www.epa.gov/PR_Notices/).

All incoming data are screened for compliance with the PR Notice. Data that are in compliance are assigned Master Record Identification Numbers (MRIDs), microfilmed and forwarded for appropriate action. Data that do not comply with the requirements of the Notice are not admitted into the system. Such data must be brought into compliance with the PR Notice before the data can be given further consideration in support of the regulatory action for which the data were submitted.

The data submitted in connection with the proposed action listed above have been found deficient with respect to the requirements of PRN 86-5. The deficiencies are identified in the enclosed comments from the Information Services Branch of the Program Management and Support Division.

Biopesticides and Pollution Prevention Division will hold associated documents for 75 days to give opportunity to resubmit the supporting data in acceptable form. If you have not done so by that time, the application and other associated documents may be administratively withdrawn from further consideration without notice to you, in accordance with policies established by PR Notice 75-4 dated August 27, 1975.

CONCURRENCES								
SYMBOL	7511C	7511C						
SURNAME	Pollard	Cully						
DATE	11/5/01	11/2/01						

Should you wish to pursue the registration of your product after the application has been withdrawn you will have to submit a complete new application.

If you choose to resubmit your data you should enclose a copy of this letter and the enclosure to identify the data as a corrected resubmission of data previously found deficient with respect to PRN 86-5. Only resubmit those items of data for which no MRID numbers were assigned. If any of your previous items was assigned an MRID number, do not resubmit that particular item of data, but simply refer to it by title and by the assigned MRID number.

Should you have any questions, please feel free to contact Mr. Driss Benmhend at (703) 308-9525.

Sincerely,

Sheryl K. Reilly, Ph.D., Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511C)

Enclosure

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7501W)
401 "M" St., S.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:

X Registration
___ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
33907-2	7/24/03

Term of Issuance:
Unconditional

Name of Pesticide Product:
Comfort Zone®

Name and Address of Registrant (include ZIP Code):

Jones-Hamilton Company
C/O Technology Science Group, Inc.
4061 North 156th Drive
Goodyear, AZ 85338

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.
Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others

This product is unconditionally registered in accordance with FIFRA sec. 3(c)(5) subject to the comments listed below:

1. Make the following label changes:

a. Add the phrase "EPA Registration No. **33907-2** to your label before you release the product for shipment

b. Add the appropriate Establishment Number to your label before you release the product for shipment

2. Submit five copies of the final printed labeling before you release this product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec.6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Unconditional registration does not eliminate the need for continual reassessment of a pesticide. If EPA determines, at any time, that additional data are required to maintain in effect, an existing registration, the Agency will require submission of such data under Section 3(c)(2)(B) of FIFRA.

Signature of the Approving Official	
Janet L. Anderson	7/24/03

COMFORT ZONE ®

EFFECTIVE MANAGEMENT OF NUISANCE FLIES OF HORSES
IN MANURE, STABLES, HORSE BARNS AND PADDOCKS

CONTROLS FLY POPULATIONS
MAKES BEDDING UNSUITABLE FOR FLY LARVAE
CONTROLS AMMONIA ODOR IN STALLS, STABLES, PADDOCKS AND MANURE PILES

ACTIVE INGREDIENT	
Sodium Bisulfate [CAS# 7681-38-1]	93.2%
OTHER INGREDIENTS.....	6.8%
Total	100.0 %

KEEP OUT OF REACH OF CHILDREN

DANGER

ACCEPTED
JUL 24 2003
Under the Federal Insecticides, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 33907-2

CAUSES IRREVERSIBLE EYE DAMAGE
HARMFUL IF SWALLOWED OR ABSORBED THROUGH THE SKIN

READ BACK PANEL PRECAUTIONARY STATEMENTS CAREFULLY

READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

Manufactured by Jones-Hamilton Co.
Walbridge, OH 43465

EPA Registration No. 33907-?

EPA Establishment No. 33907-OH-1

NET CONTENTS: 50 lbs

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Causes irreversible eye damage. Do not get in eyes or on skin, or on clothing. Wear goggles, or face shield and rubber gloves when handling. Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15 - 20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING:

- Take off contaminated clothing
- Rinse skin immediately with plenty of water for 15 - 20 minutes
- Call a poison control center or doctor for treatment advice

IF SWALLOWED:

- Call a poison control center or doctor for treatment advice
- Have person sip a glass of water if able to swallow
- Do not induce vomiting unless told to do so by a poison control center or doctor
- Do not give anything by mouth to an unconscious person.

Have the product container with you when calling a poison control center or doctor, or going for treatment You may also contact American Association of Poison Control Centers at 1-800 -222-1222 for emergency medical treatment information.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

PHYSICAL & CHEMICAL HAZARDS

Never use with products containing chlorine. Never use or mix with other chemicals.

STORAGE AND DISPOSAL STATEMENTS

Do not contaminate water, food or feed by storage or disposal

PESTICIDE STORAGE:	Store in original container in a cool, dry area.
PESTICIDE DISPOSAL:	Pesticides are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.
CONTAINER DISPOSAL:	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned stay out of smoke.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

FOR ALL APPLICATIONS OF COMFORT ZONE® IN HORSE STALLS, STABLES, PADDOCKS & MANURE PILES

COMFORT ZONE® is a novel fly control product for use in stables, horse barns, paddocks and any other enclosure for horses where manure accumulates and becomes a breeding source for house flies and stable flies.

REMOVE HORSES FROM STALLS WHILE APPLYING COMFORT ZONE®

1]. For best results, apply COMFORT ZONE® daily.

2]. Use COMFORT ZONE® on **any kind of bedding material** (wood shavings, sawdust, wheat straw, etc.)

3]. Apply COMFORT ZONE® evenly throughout the stall while concentrating more of the product on the wet spots. The following rates are representative to be used as a guide.

STALL SIZE	COMFORT ZONE®
10' x 10'	1 pound or 1⅓ cups
12' x 12'	1½ pounds or 2 cups
15' x 15'	2 lbs or 2⅔ cups

4]. For additional control, apply COMFORT ZONE® directly to manures piles and/or in paddocks at the rate of 1 pound per 100 square feet.

5]. COMFORT ZONE® will not harm rubber mats

WARRANTY

Jones-Hamilton Co., warrant that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing, presence of other materials, cleaning practices, incompatibility with other chemicals, pre-existing conditions and other conditions influencing the use of the product are beyond the control of the Seller. Buyer assumes all risks associated with the use, storage and handling of this material not in strict accordance with the directions given herewith. Except as otherwise expressly provided herein, the Seller makes no representation or warranty of any kind, express or implied, as to the merchantability, fitness for a particular purpose, or any other matter with respect to the material. To the extent permitted by law, under no circumstances shall the Seller be liable to the Buyer for consequential, punitive, special, exemplary or incidental damages.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SEP 1 0 2001

Iain Weatherston
Jones-Hamilton Company
c/o Technology Science Group, Inc.
4061 North 156th Drive
Goodyear, AZ 85338

Subject: Application for Registration of the Product Comfort Zone®
EPA Registration Symbol: 33907-E
Your Submission of January 2, 2001

Dear Mr. Weatherston:

The support documents for the registration of the product listed above were reviewed, and a copy of the review summary is enclosed.

BPPD concluded that the data submitted is insufficient to support the application for registration of Comfort Zone®. There are several deficiencies in the chemistry, manufacturing process and product formulation data. The Confidential Statement of Formula (CSF) and the label are unacceptable and need to be revised and submitted. Please refer to the enclosed document for details on our reviews and recommendations. These deficiencies must be resolved before this application can be given further consideration.

If you have any questions regarding this action, please contact Driss Benmhend, the Regulatory Action Leader for this project at (703) 308-9525.

Sincerely,

Sheryl K. Reilly Ph. D., Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511C)

Enclosures

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 29 2001

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Science Review in Support of the Registration of Comfort Zone® (EPA File Symbol No. 033907-E) containing 93.2% Sodium Bisulfate (Chemical No. 073201) as Its Active Ingredient. Review of Product Chemistry Studies, Product Performance Studies, and Waiver Requests for Acute Toxicity and Non-Target Organism Studies. DP Barcode D273401; Case No. 070049; Submission No. S592783; MRID Nos. 453018-01, -02, and -03

FROM: Russell S. Jones, Ph.D., Biologist
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

THRU: Freshteh Toghrol, Ph.D., Senior Scientist F. Toghrol
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

TO: Driss Benmhend, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

ACTION REQUESTED

On behalf of Jones-Hamilton Company, Iain Weatherston requests registration of Comfort Zone® (EPA File Symbol No. 33907-E), containing 93.2% sodium hydrogen sulfate (sodium bisulfate) as its active ingredient. The product is a Technical Grade Active Ingredient (TGAI) that is intended for use as an end-use product (EP). The product is intended for non-food use control of house flies and stable flies in stables, horse barns, horse trailers, paddocks and any other enclosures for horses where manure may accumulate. In support of the registration, the registrant has submitted product chemistry studies (MRID 453018-01), efficacy studies (MRID 453018-02), a request for waivers from the data requirements for acute toxicity and non-target organisms (no MRID no.) and a "white paper" containing miscellaneous information pertaining to the active ingredient, a Confidential Statement of Formula (dated 01/06/2001), and a proposed label.

CONCLUSIONS AND RECOMMENDATIONS

1. The submitted product chemistry data do not support the registration of Comfort Zone® (containing 92.30% sodium bisulfate as its active ingredient) due to deficiencies in the description of the manufacturing process (OPPTS 830.830.1600, 830.1620, and 830.1650; Subdivision M 151-11), the discussion of the formation of impurities (OPPTS 830.1670; Subdivision M 151-12), preliminary analysis data (OPPTS 830.1670; Subdivision M 151-13), analytical methods (OPPTS 830.1800; Subdivision M 151-16), and physical/chemical properties . The CSF is also unacceptable.

2. The description of the manufacturing process (OPPTS 830.830.1600, 830.1620, and 830.1650; Subdivision M 151-11) is unacceptable, but upgradable. The information submitted by the registrant is little more than a brief overview. To upgrade the manufacturing process to acceptable, the registrant must more fully explain certain details of the manufacturing process. Specifically, more information is required regarding:
   (i) the amounts (e.g. kg, lbs, etc.) of reactants and products used/produced in the synthesis of a typical batch;
   (ii) the nature of the reaction vessels (i.e,. stainless steel, etc,);
   (iii) sources of the starting materials; and
   (iv) QA/QC procedures.

3. The registrant did not submit a discussion of the formation of impurities (OPPTS 830.1670; Subdivision M 151-12). In lieu of a discussion, a specification sheet from the manufacturer of the active ingredient was submitted. The specification sheet lists "typical" concentrations and ranges for components of the TGAI. These data are inappropriate to be used as a substitute for a discussion of the formation of impurities. A full discussion of the potential for unintentional impurities to be formed during the manufacturing process (i. e. [redacted]) or carried over into the product from the starting materials (see list of impurities on Jones and Hamilton SBS Specification Sheet) must be submitted.

4. No preliminary analysis data (OPPTS 830.1670; Subdivision M 151-13) were submitted. Since the product is manufactured via an integrated process (i. e. the active is not purchased from an EPA-registered source) five-batch preliminary analysis data are required.

5. No analytical method (OPPTS 830.1800; Subdivision M 151-16) was submitted . In lieu of an analytical method the registrant indicated that it requested a waiver from the data requirements for an analytical method (MRID 453018-01, Volume 33907-2, Product Chemistry, p. 6), and that the full text of the waiver was placed in (No MRID No., Volume 33907-4, Request for Waivers of Specific Data Requirements, no page

specified). A thorough examination of Volume 33907-4 showed that no such waiver request was submitted. Since the product is manufactured via an integrated process and the active ingredient is not purchased from an EPA-registered source, an analytical method is required. The description of the analytical method must include precision and accuracy data, and representative data and chromatograms. This method must be used to generate the five-batch preliminary analysis data.

6. The physical/chemical properties data (OPPTS 830.6315 and OPPTS 830.6316; Subdivision M 151-17) are incomplete. Solubility (OPPTS 830.7840 or 830.7860), vapor pressure (OPPTS 830.7950), flammability (OPPTS 830.6315) and explodability (OPPTS 830.6316) data , or statements indicating why these data are not applicable are required under 40 CFR §158.690 because the TGAI/EP is manufactured by the registrant. The registrant must submit this information/data.

7. The proposed CSF is unacceptable and must be revised. The revised CSF must include the following information: (i) the "Basic Formulation" box must be checked off; and (ii) the bulk density data should be changed to 82-84 lbs/cubic foot. Since the end-use product is a solid, the currently listed "11.01 lbs/gal" data is not relevant.

8. The registrant must submit a revised label. The description of the active ingredient must be changed to "Sodium bisulfate" to agree with the description of the active ingredient listed on the CSF.

9a. The registrant does not explicitly discuss a mode of action for the active ingredients against flies in the labeled use sites. Suggested modes of action are discussed in the submitted efficacy studies (see Conclusion 12b) but no quantitative data were subited to support the proposed mode of action against flies in areas where horses are enclosed. Proposed mode(s) of action must be supported by quantitative data.

9b. Toxicity data/information regarding sodium bisulfate contained in the *Mineral Acids RED* (EPA-738-F-93-025, dated 12/1993), as well as other data/information submitted by the registrant in the *Request for Waivers of Specific Data Requirements* (No MRID No., Volume 33907-4, pp. 6 and 7) are acceptable to support waivers from the requirements for acute toxicity studies. No additional acute toxicity studies/data are required.

9c. Although no specific waiver request for acute oral toxicity was submitted, the data/information contained in the *Mineral Acids RED* may be bridged to support a waiver from acute oral toxicity studies. BPPD notes that the proposed non-food use of Comfort Zone® (control of house flies and stable flies in stables, horse barns, horse trailers, paddocks and any other enclosures for horses where manure may accumulate) renders acute oral and/or dietary human exposure highly unlikely.

10a. Data/information regarding sodium bisulfate contained in the *Mineral Acids RED* (EPA-738-F-93-025, dated 12/1993), as well as other data/information submitted by the registrant in the *Request for Waivers of Specific Data Requirements* (No MRID No., Volume 33907-4, p. 7) are acceptable to support waivers from the requirements for non-target organism studies. No additional non-target organism studies/data are required.

10b. Although no specific waiver request for non-target insects was submitted, the data/information contained in the *Mineral Acids RED* may be bridged to support a waiver from non-target insect studies. BPPD notes that the proposed use of Comfort Zone® (control of house flies and stable flies in stables, horse barns, horse trailers, paddocks and any other enclosures for horses where manure may accumulate) renders non-target insect (e. g. honey bees) exposure unlikely.

11. A "white paper" on sodium bisulfate [written by the consultant for the registrant (Iain Weatherston); MRID 453018-03], contained information already cited in either the *Mineral Acids RED* or the request for waivers. This volume additionally contained MSDS for sodium bisulfate and technical specification/advertising information published by the registant. No DER was written for this volume.

12a. The registrant submitted two non-guideline product performance (efficacy) studies. The studies suggest that application of [redacted] reduces numbers of flies in stalls of horse barns. The data support claims that the product can reduce populations of flies within the labeled use sites (see Conclusions 9b and 10b above).

12b. The mode of action of sodium bisulfate against flies is uncertain. Based on the submitted efficacy studies, it is uncertain whether sodium bisulfate application renders a treated area unattractive to flies or whether a toxic mode of action is involved. No data were presented in either study pertaining to larval development in manure treated with sodium bisulfate. Although the study authors cited other technical literature stating that sodium bisulfate applications reduced manure pH to a level that is "toxic to housefly larvae and prevents their development," no quantitative data were submitted to support any particular mode of action.

12b. BPPD notes that neither study identified the species of flies that were captured on the sticky tapes. Since no fly species were identified, the registrant must remove the phrase "house and stable flies" from the product label. The deleted text may be substituted with the phrase "nuisance flies of horses" or some other similar phrase that does not identify a particular species of fly. Alternatively, the registrant may submit additional efficacy studies wherein he species of flies controlled by the product are identified.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SEP 10 2001

Iain Weatherston
Jones-Hamilton Company
c/o Technology Science Group, Inc.
4061 North 156th Drive
Goodyear, AZ 85338

Subject: Application for Registration of the Product Comfort Zone®
EPA Registration Symbol: 33907-E
Your Submission of January 2, 2001

Dear Mr. Weatherston:

The support documents for the registration of the product listed above were reviewed, and a copy of the review summary is enclosed.

BPPD concluded that the data submitted is insufficient to support the application for registration of Comfort Zone®. There are several deficiencies in the chemistry, manufacturing process and product formulation data. The Confidential Statement of Formula (CSF) and the label are unacceptable and need to be revised and submitted. Please refer to the enclosed document for details on our reviews and recommendations. These deficiencies must be resolved before this application can be given further consideration.

If you have any questions regarding this action, please contact Driss Benmhend, the Regulatory Action Leader for this project at (703) 308-9525.

Sincerely,

Sheryl K. Reilly Ph. D., Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511C)

Enclosures

COMFORT ZONE ®

EFFECTIVE MANAGEMENT OF HOUSE AND STABLE FLIES
IN MANURE, STABLES, HORSE BARNS, PADDOCKS AND HORSE TRAILERS

CONTROLS FLY POPULATIONS
MAKES BEDDING UNSUITABLE FOR FLY LARVAE
CONTROLS AMMONIA ODOR IN PADDOCKS AND MANURE PILES

Sodium bisulfate ok

ACTIVE INGREDIENT	
~~Sodium hydrogen sulfate [CAS# 7681-38-1]~~	93.2%
OTHER INGREDIENTS	6.8%

KEEP OUT OF REACH OF CHILDREN

DANGER

CAUSES EYE & SKIN DAMAGE
HARMFUL IF SWALLOWED

READ BACK PANEL PRECAUTIONARY STATEMENTS CAREFULLY

READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

Manufactured by Jones-Hamilton Co.
Walbridge, OH 43465

EPA Registration No. 33907-RE

EPA Establishment No. 33907-OH-1

NET CONTENTS: 50 lbs

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive, causes eye and skin damage. Do not get in eyes or on skin, or on clothing. Wear goggles, or face shield and rubber gloves when handling. Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15 - 20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING:

- Take off contaminated clothing
- Rinse skin immediately with plenty of water for 15 - 20 minutes
- Call a poison control center or doctor for treatment advice

IF SWALLOWED:

- Call a poison control center or doctor for treatment advice
- Have person sip a glass of water if able to swallow
- Do not induce vomiting unless told to do so by a poison control center or doctor
- Do not give anything by mouth to an unconscious person.

Have the product container with you when calling a poison control center or doctor, or going for treatment You may also contact 1-800 -xxx-xxxx for emergency medical treatment information.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

PHYSICAL & CHEMICAL HAZARDS

Never use with products containing chlorine. Never use or mix with other chemicals.

STORAGE AND DISPOSAL STATEMENTS

Do not contaminate water, food or feed by storage or disposal

PESTICIDE STORAGE: Store in original container in a cool, dry area.

PESTICIDE DISPOSAL: Pesticides are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned stay out of smoke

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

FOR ALL APPLICATIONS OF COMFORT ZONE® IN HORSE STALLS, PADDOCKS, TRAILERS & MANURE PILES

COMFORT ZONE® is a novel fly control product for use in stables, horse barns, horse trailers paddocks and any other enclosure for horses where manure may accumulate and become a breeding source for house flies and stable flies. The active ingredient in COMFORT ZONE® is approved by the FDA as a general purpose feed additive for animal feeds. Not to be sold

1]. For best results a daily application is recommended.

2]. COMFORT ZONE® can be used on **any kind of bedding material** (wood shavings, sawdust, wheat straw, etc.]

3]. Apply COMFORT ZONE® evenly throughout the stall while concentrating more of the product on the wet spots. The following rates are representative and can be used as a guide.

STALL SIZE	COMFORT ZONE®
10' x 10'	1 pound or 1⅓ cups
12' x 12'	1½ pounds or 2 cups
15' x 15'	2 lbs or 2⅔ cups

4]. For additional control, apply COMFORT ZONE® directly to manures piles and/or in paddocks at the rate of 1 pound per 100 square feet.

5]. COMFORT ZONE® will not harm rubber mats

- Appendix) in which it stated that "the Agency is not currently requiring toxicology data on sodium bisulfate."

Hypersensitivity Study

A waiver is requested for the hypersensitivity study based on:

- the Agency have previously decided in the reregistration process that all acute toxicity data for sodium bisulfate were waived or not required based on the extensive documentation provided in the literature on this chemical [footnote1 to the Acute Toxicity table on page 13 of the Mineral Acids RED.
- the footnote [3] in the Acute Toxicity table on page 13 of the Mineral Acids RED that if the eye irritation is category I then the hypersensitivity study is not required.
- the statement made in the 1992 letter from Bruce Sidwell (at that time Section 3 Chief in SRRD) to Jim Hill at CSMA (copy included in the Appendix) in which it stated that "the Agency is not currently requiring toxicology data on sodium bisulfate."

Teratogenicity Study [152-23]

A waiver is requested for the teratogenicity study based on:

- the substance cannot be used in any toxicological test involving living animals or living tissue because of its corrosive nature. The corrosivity of the material in such media would superceed any potential for teratogenicity, oncogenicity, genotoxicity, neurotoxicity or reproductive effect
- the Agency's statement [page 13 of the RED] that "additional toxicology studies are not required for sodium bisulfate based on current use patterns and the fact that it forms ubiquitous metabolic products, sodium and sulfate, that are of little toxicological concern. This applies only to the technical chemicals and does not apply to end-use product data requirements." However, in the case of COMFORT ZONE® the end-use product is the technical material and the intended use pattern is non food hence the Agency's statement is applicable.

Avian Acute Toxicity [154-6]
Avian Dietary Toxicity [154-7]
Freshwater Fish Toxicity [154-8]
Freshwater Invertebrate Toxicity [154-9]

A waiver is requested for the above four studies based on:

- the Agency's statement [page 17 of the Mineral Acids RED] that for current uses [except potato vine desiccation use of sulfuric acid] that "since there is sufficient information regarding the toxic and corrosive nature of the mineral acids, all avian and aquatic studies have been waived for these uses." Jones-Hamilton believes that the Agency's statement is also applicable since the intended use pattern of COMFORT ZONE®

WAIVER REQUEST FOR SPECIFIC DATA REQUIREMENTS

Acute Dermal Toxicity [151-11]

A waiver of the acute dermal toxicity study is requested, based on:

- its current widespread use in commerce in the following industries, metal treating, chemical manufacturing, water treatment, leather goods, paper manufacture and in electronics. It is also used in animal feed additives and in food processing.
- a DOT skin corrosivity test [copy included in the Appendix] in which it was found to be neither corrosive nor destructive to the skin of rabbits.
- the statement made in the 1992 letter from Bruce Sidwell (at that time Section 3 Chief in SRRD) to Jim Hill at CSMA (copy included in the Appendix) in which it stated that "the Agency is not currently requiring toxicology data on sodium bisulfate."
- the fact that the Agency believes that the acute dermal toxicity endpoint is >10,000 g/kg based on information in Dangerous Properties of Industrial Materials 7th Edition [N. I. Sax & R. J. Lewis, Sr 1989, p. 2770] Van Norstrand Reinhold, New York.
- the Agency have previously decided in the reregistration process that all acute toxicity data for sodium bisulfate were waived or not required based on the extensive documentation provided in the literature on this chemical [footnote1 to the Acute Toxicity table on page 13 of the Mineral Acids RED.

Acute Inhalation Toxicity [151-12]

A waiver of the acute inhalation toxicity study is requested based on:

- the Agency have previously decided in the reregistration process that all acute toxicity data for sodium bisulfate were waived or not required based on the extensive documentation provided in the literature on this chemical [footnote1 to the Acute Toxicity table on page 13 of the Mineral Acids RED.
- the statement made in the 1992 letter from Bruce Sidwell (at that time Section 3 Chief in SRRD) to Jim Hill at CSMA (copy included in the Appendix) in which it stated that "the Agency is not currently requiring toxicology data on sodium bisulfate."

Primary Eye Irritation [151-13]

A waiver is requested for the primary eye irritation study based on:

- the Agency have previously decided in the reregistration process that all acute toxicity data for sodium bisulfate were waived or not required based on the extensive documentation provided in the literature on this chemical [footnote1 to the Acute Toxicity table on page 13 of the Mineral Acids RED.
- the statement made in the 1992 letter from Bruce Sidwell (at that time Section 3 Chief in SRRD) to Jim Hill at CSMA (copy included in the

Effect of sodium bisulfate on ammonia concentration, fly population, and manure pH in a horse barn

Corinne R. Sweeney, DVM; Sue McDonnell, PhD; Gail E. Russell; Mac Terzich, DVM

Objective—To evaluate the effectiveness of altering the pH of manure with sodium bisulfate, thereby decreasing ammonia concentration and fly population in a horse barn environment.

Animals—4 mixed-breed pony stallions.

Procedure—The 4-week study was scheduled with 2 weeks of treatment (with 2 application rates) and 2 weeks with no treatment (control weeks). During treatment weeks, sodium bisulfate was applied daily to the top of the bedding and straw, then spread on top. Ponies were kept in the stalls 24 hours a day during the 7-day test period and stall cleaning was not done. On day 7 of each week, ammonia concentration, manure pH, number of flies on a fly tape, and fly-evasive behavior patterns were determined.

Results—Sodium bisulfate applied to the horse stall environment daily of either 2.3 or 4.5 kg/9.3 m² (5 or 10lb/100 ft²) decreased ammonia concentration, manure pH, and number of flies in the stall environment, compared with a control period with no sodium bisulfate. Fly-evasive behavior patterns of ponies occupying the stalls, including tail swishes, head tosses, and kicks/strikes, were decreased during the period of sodium bisulfate application.

Conclusion—Sodium bisulfate may be an effective method of decreasing ammonia concentration and may serve as a method of fly control in horse barns. (*Am J Vet Res* 1996;57:1795–1798)

Volatilization of ammonia has been attributed to microbial decomposition of nitrogenous compounds,[1,2] principally urea in equine manure and uric acid in poultry litter. Manure pH has a decisive role in NH_3 volatilization.[3] Once formed, the free ammonia will be in 1 of 2 forms: as the uncharged NH_3 species or as ammonium ion (NH_4^+), depending on pH of the medium. Ammonia concentration increases with increasing pH.[4] Ammonia release is small when manure pH is < 7.0, but substantial when pH is > 8.0. Acidification has proven to be an efficient method of reducing NH_3 losses in cattle slurry. Ammonia losses increased progressively with increasing pH and temperature.[3] In Northern Ireland, slurry pH of 5.5, 6.0, and 6.5 resulted in reduction of NH_3 loss of > 85, 90, and 75%, respectively. Other investigators in The Netherlands have reported that pH of 4.5 to 5.0 is needed to obtain similar reductions.[5]

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Several chemicals have been tested for their ability to control or reduce ammonia release from poultry litter. Examples include paraformaldehyde, clinoptilolite, yucca sponin, acetic and propionic acids, sorbic acid, gentian violet, and calcium propionate.[1] They act by either inhibiting microbial growth and, hence, uric acid decomposition, or by combining with the released ammonia to neutralize it.[2] Phosphoric acid treatment of poultry litter lowered pH and decreased ammonia concentration, compared with values for controls.[6] Sodium bisulfate, a dry acid similar in size and consistency to coarse salt crystals, is used to reduce ammonia concentration and provide an environment in which bacteria cannot grow by lowering the pH in poultry litter. Because of its efficacy in lowering the ammonia concentration in poultry facilities, sodium bisulfate might be effective in controlling ammonia[1] in a horse barn environment. Lowering the pH of manure has also been documented to decrease the fly population in poultry houses because manure pH of 2 is toxic to fly larvae.[6] The objective of the study reported here was to evaluate the effectiveness of altering the pH of manure with sodium bisulfate, thereby decreasing ammonia concentration and fly population in a horse barn environment.

Materials and Methods

Horses—Four mixed-breed pony stallions of various body weights (mean, 185.9 ± 18.9 kg) and age ranging from 3 to 20 (mean, 10.5 ± 8.3) years were studied. Ponies were housed in individual 3 × 3-m box stalls in a bank barn with concrete floors and cinder block walls; no other animals were housed there. Ponies were observed daily for any cutaneous lesions or signs of lameness. Husbandry and experimental use of ponies were conducted in accordance with the National Institutes of Health *Guide for the Care and Use of Laboratory Animals*. Experimental protocols were reviewed and approved by the University of Pennsylvania Institutional Animal Care and Use Committee.

Study design—The 4-week study, from Aug 8 through Sept 4, 1995, was scheduled as: week 1, control week—no sodium bisulfate application; week 2, treatment week—sodium bisulfate application at 4.5 kg/9.3 m²; week 3, control week—no sodium bisulfate application; and week 4, treatment week—sodium bisulfate application at 2.3 kg/9.3 m².

All testing was done on day 7 of each week. On day 1 of weeks 2 and 4 (treatment weeks), sodium bisulfate[a] was applied to the stall floor, then covered with approximately 15 kg of straw bedding. On days 2 through 7, sodium bisulfate was applied daily to the top of the bedding and approximately 2 kg of straw was then spread on top. Ponies were kept in the stalls 24 h/d during the 7-day test period and stall cleaning was not done. All barn windows were closed during the study, and barn doors were opened only to allow entry/exit of the animal caretaker and the authors. Traffic by these individuals was consistent from week to

chickens.[6,7,14] For human beings, 25 ppm ammonia for an 8-hour exposure[8] or 35 ppm for exposure up to 15 minutes is considered a threshold value.[1] For animals in confinement buildings, 10 ppm is considered a threshold limit value.[8] Increased concentrations of ammonia in the environment have been documented to affect the health of animals. Rate of gain in young pigs was reduced by 12% during exposure to aerosolized ammonia at 50 ppm and by 30% at 100 ppm.[13] Turkeys maintained in the presence of 10 ppm of NH_3 had deterioration of their normal mucociliary apparatus. Excess mucus production, matted cilia, and areas of deciliation in the tracheal tissues were detected in birds exposed to 10 ppm of NH_3.[12] Ammonia at a concentration of 10 ppm affected the quantitative clearance of *Escherichia coli* from lungs, air sacs, and livers of turkeys aerosol-vaccinated against *E coli*.[13] To the author's knowledge, no reports on the adverse effects or toxic concentrations of ammonia for horses have been published. Most likely, concentrations toxic to other mammalian species would be toxic to horses. Under the housing conditions of this study, ammonia concentrations in 1 pony's stall exceeded 10 ppm during both control weeks. Clinical signs suggesting altered respiratory tract function were not evident in this pony. Although ammonia in most horse barns may not be at toxic concentrations, it is well known that the horse's natural stall environment of straw bedding and hay as a foodstuff provides appreciable respiratory challenge to all horses and is responsible for numerous airway disorders, including chronic obstructive airway disease. Veterinarians are most concerned about ammonia's effects on neonatal and young foals because of their immature respiratory systems, increased susceptibility to diseases, and increased inhalation of ammonia owing to foal's propensity to spend a large amount of time in lateral recumbency.

Research and regulatory agencies have indicated increased interest in ammonia as a potential air pollutant.[14] Confinement animal units produce large volumes of animal waste on small land areas. Odors and other undesirable effects are persistent problems,[17] particularly because in many areas, new housing developments are being constructed in rural areas where flock/livestock production already exists.

Although the need to control production of ammonia in broiler houses continues,[4] horse owners are equally concerned as more nonhorse owners voice displeasure over manure odors and flies associated with nearby horse farms. Studies[18] have indicated that equine facilities are habitats suitable for large-scale breeding of stable as well as house flies. Mean stable fly pupal production and weight has been documented to be greatest in horses, compared to cattle, swine, and chicken, manure.[19] Flies serve as a nuisance to horses and to people working with horses. The feeding of the face fly induces ocular lacrimation, damages conjunctival tissues, and may expose horses to fly-borne pathogens. Flies are a vector for the parasites *Habronema* and *Onchocera* spp[20,21] and have been associated with nonspecific and eosinophilic conjunctivitis.

In our study, we monitored the ponies' fly-evasive behaviors. Behavioral responses elicited by insect activity are well known in domestic livestock.[22] Recording fly-induced movements as a means of monitoring fly populations has been used in grazing cattle.[22] Ear movements, skin twitches, tail movements, and kicking and raising of limbs were viewed as fly-induced reactions to stable flies.[22] Ear flap rate was found to be positively correlated with number of face flies.[22] Quantitative studies[23-25] in cattle have indicated that behavioral responses of tail switching, ear flapping, and head tossing are positively correlated with insect activity.

Many methods are used to monitor fly populations in the environment and include sticky tape, spot card, baited jug trap, grill count, and subjective visual index.[26] The sticky tape is a simple quantitative method to monitor flies in a horse barn environment and is frequently used in commercial and recreational horse barns as a means to control flies. Our study did not determine the types of flies attracted to the sticky fly tape, though all were similar in appearance. The association of the decrease in numbers of flies on the sticky tape with periods of decreased fly-evasive behavior suggests that the flies that were caught on the tape were of the type to "bother" the ponies. Although a herd of 10 horses was pastured within 150 ft of the ponies' barn, their numbers and pasture conditions remained unchanged during the 4-week study.

Development of housefly larvae is dependent on manure pH and temperature. Manure pH of 2 is considered toxic to housefly larvae and prevents development.[4] The sodium bisulfate lowered the manure pH to this toxic value and would have prevented flies from hatching in this manure. The range of time for larval development at the environment temperature of 35 C (95 F) is 9 to 22 days, and at 20 C (68 F) is 6 to 8 days.[27] The average daily temperature throughout this study was 24.8 to 27.7 C (76.6 to 81.9 F). Testing was done on day 7. The decrease in fly numbers and fly-evasive behaviors on day 7, the day of testing, may have been attributable to decreased larval development secondary to low manure pH. One could speculate that, not only could fly larvae not survive in the acidic manure, but that the change in pH made the manure less attractive as a breeding site to flies already in the area. Water content of manure does not influence fly larval development unless the manure is extremely liquid or "soupy."[27] Our ponies' manure was of normal consistency, and thus, water content was not thought to have influenced fly development.

Our findings suggest that sodium bisulfate would be an effective method of decreasing ammonia concentration and serve as a method of fly control in horse barns.

[4]Pitts C, Department of Entomology, College of Agricultural Sciences, Pennsylvania State University: Personal communication, 1995.

[5]Jones-Hamilton Co, Walbridge, Ohio.

[6]National Climatic Data Center, US Department of Commerce, Asheville, NC.

[8]Mine Safety Appliance Co, Pittsburgh, Pa.

[9]Lab Safety Co, Janesville, Wis.

References

1. Burnett WE, Dondero NC. Microbiological and chemical changes in poultry manure associated with decomposition and odor generation. *Animal waste management*, Ithaca, NY: in *Proceedings*. Cornell University Conference on Agricultural Waste Management Syracuse, 1969:271–291.

2. Carlile FS. Ammonia in poultry houses: a literature review. *World Poult Sci J* 1984;40:99–113.

week. On the evening of day 7 of each week, stalls were washed and the ponies were housed on pasture overnight. All procedures were the same during weeks 1 and 3 (control weeks), except that sodium bisulfate was not applied. Fly repellents were not applied during the study. Throughout the 4-week study, 10 female horses were pastured in an approximately 25-acre field with its closest fence line 150 ft from the barn housing the study ponies. Average ambient and the high and low local temperatures were determined for each week from data obtained from the National Climatic Data Center.[c]

Ammonia determination—Ammonia concentration was measured by use of a handheld piston digital suction pump[d] and Auer ammonia detection tubes.[e] The tubes had a range of 2 to 500 µl/L (sensitivity limit of 1 µl/L), with a direct reading scale on the tube. For recording the ammonia concentration, the device was held about 15 cm above the region in the stall with the dirtiest bedding (most packed moist manure) and a single reading was obtained.

Manure pH determination—A 60-ml volume of manure was collected from an area in the pony's stall with packed feces, bedding, and urine and was mixed with an equal volume of distilled water. A pH meter was submerged in the manure slurry and the pH was recorded. The pH meter was washed, then calibrated, using distilled water, and the recording was repeated.

Fly evaluation—Fly tapes were hung from the ceiling of the center of each stall on the morning of day 7. After 7 hours, tapes were removed, and flies adhering to the sticky surface were counted. Each pony was videotaped for one 9-hour session on day 7. The tapes were coded so that the evaluator (SM) did not know which study week tape was being viewed. Quantitative measures included tail swish, head toss, kick/strike frequency, and total fly-evasive behavior (total count of tail swish, head toss, and kick/strike). A tail swish was defined as a moving of the tail past its vertical position. A head toss was defined as a lifting up or lowering of the nose past the normal plane. A kick/strike was defined as a raising of the hind (kick) or front (strike) foot.

Statistical analysis—A Friedman's nonparametric repeated measures test was used to determine whether ammonia values, manure pH, number of flies, and hourly frequency of fly-evasive behaviors were different between study weeks. The Dunn's multiple comparisons test was used for pairwise testing. Values were considered significant at $P < 0.05$.

Results

Ammonia determination—Ammonia concentration was lowered during sodium bisulfate treatment (Table 1). It was not detectable in any of the 4 stalls after the 4.4-kg sodium bisulfate treatment and in 3 of the 4 stalls after the 2.3-kg sodium bisulfate treatment. Although the Friedman's nonparametric repeated measures test indicated significant variation among the groups ($P = 0.0016$), the small sample size prevented the Dunn's multiple comparison test from revealing significant differences when groups were compared in pairwise fashion.

Table 1—Ammonia concentration, manure pH, and number of flies in a barn environment after treatment of the stall with sodium bisulfate

Variable	Ammonia (ppm)	Manure pH	No. of flies on tape
Week 1–Control	5.25 (3.5–22.5)	8.55 (8.0–8.7)*	48.0 (23.0–65.0)*
Week 2–Sodium bisulfate (4.5 kg)	0 (0.0–0.0)	1.8 (1.4–2.0)*	7.5 (1.0–16.0)
Week 3–Control	5.0 (2.5–18.0)	8.55 (7.5–8.9)	43.5 (17.0–48.0)
Week 4–Sodium bisulfate (2.3 kg)	0.0 (0.0–0.75)	2.0 (1.5–2)	3.0 (1.0–8.0)*
P value	0.016	0.0009	0.0009

*Indicates significant difference between groups as determined by the Dunn's multiple comparisons test.
P value is for the column variation, as determined by the Friedman's nonparametric repeated measures test.
Data are expressed as median, with range in parenthesis.

Manure pH determination—Manure pH was lower during the sodium bisulfate treatment periods, compared with the control week values (Table 1). The week-to-week variation was significant ($P = 0.0009$). The Dunn's multiple comparisons test indicated significant difference between week 1 (control) and week 2 (treated).

Fly evaluation—Numbers of flies collected on the fly tape were decreased during both sodium bisulfate treatment periods, compared with control week numbers (Table 1). The Dunn's multiple comparisons test indicated significant difference between week 1 (control) and week 4 (treated).

Hourly frequency rates for tail swish, head toss, kick/strike, and total fly-evasive behavior were calculated (Table 2). All hourly frequency rates were lower during both sodium bisulfate treatment periods. Although the Friedman's nonparametric repeated measures test indicated significant variation among the groups for tail swishes, the small sample size prevented the Dunn's multiple comparisons test from revealing significant differences when groups were compared in pairwise fashion. Although the difference in frequency rates for head toss, kick/strike, and total fly-evasive behavior were not statistically significant, review of the data indicated a strong trend toward decrease in each activity during the sodium bisulfate treatment periods.

Table 2—Results of fly-evasive behavior of ponies in a barn environment after treatment of the stall with sodium bisulfate

Variable	No. of tail swishes	No. of head tosses	No. of kicks/strikes	Total No. of fly-evasive behaviors
Control	44.25 (11.0–336.0)	3.5 (0.0–45.0)	8.0 (0.0–84.0)	72.75 (11.5–427.5)
Sodium bisulfate (4.5 kg)	1.25 (0.0–8.0)	0.5 (0.0–8.0)	0.0 (0.0–1.0)	1.25 (1.0–14.0)
Control	86.25 (0.0–295.0)	7.5 (0.0–48.0)	12.75 (0.0–23.0)	118.5 (0.5–331)
Sodium bisulfate (2.3 kg)	0.0 (0.0–6.75)	3.0 (0.0–3.0)	0.0 (0.0–1.0)	4.5 (3.0–6.75)
P value	0.0329	0.1287	0.1053	0.0678

Data are hourly frequency rate and are expressed as median with range in parenthesis.
See Table 1 for key.

Pony observation—Signs of cutaneous lesions or lameness were not evident during the study. Ponies ate hay placed on the floor in the stall corner. Their eating habits usually resulted in spreading the hay around 25% of the stall over the soiled manure. Cutaneous muzzle lesions or signs of gastrointestinal tract dysfunction were not apparent during the study. Abnormalities of appearance, actions, or attitude of any pony were not observed during the 4-week study.

Temperature—Average ambient and the high and low temperatures were not statistically different during the sodium bisulfate treatment periods, compared with control weeks. Average daily temperature for the 4 weeks ranged from 24.8 to 27.7 C (76.6 to 81.9 F).

Discussion

Ammonia is a known respiratory tract irritant in human beings,[7,8] rats,[9] pigs,[10] cows,[11] turkeys,[12,13] and

3. Ivos J, Asaj A, Marjanovic LJ, et al. A contribution to the hygiene of deep litter in the chicken house. *Poult Sci* 1966;45:676–683.

4. Carr LE, Wheaton FW, Douglass LW. Empirical models to determine ammonia concentrations from broiler chicken litter. *Trans Am Soc Agric Engineer*, 1990;33:1337–1342.

5. Bussink DW, Huijsmans JFM, Ketelaars JJMH. Ammonia volatilization from nitric-treated cattle slurry surface applied to grassland. *Neth J Agric Sci* 1994;42:293–309.

6. Reece FN, Lott BD, Deaton JW. Ammonia in the atmosphere during brooding affects performance and carcass quality. *Poult Sci* 1980;59:486–488.

7. Moum SG, Seltzer W, Goldhaft TM. A simple method of determining concentrations of ammonia in animal quarters. *Poult Sci* 1974;48:347–348.

8. Mårtensson L. Respiratory hazards in houses for laying hens. In: McDuffee HE, ed. *Agricultural health and safety: workplace, environment, sustainability*. Boca Raton, Fla: CRC Press, 1995;563–569.

9. Dalhamn T. Mucus flow and ciliary activity in tracheas of healthy rats and rats exposed to respiratory irritant gases. *Acta Physiol Scand* 1956;36(Suppl 123):1–161.

10. Drummond JG, Curtis SE, Simon J. Effects of atmospheric ammonia on pulmonary bacterial clearance in the young pig. *Am J Vet Res* 1978;39:211–212.

11. Humphreys DJ. Minerals and organic substances. In: *Veterinary toxicology*. 3rd ed. Philadelphia: WB Saunders Co, 1988;16.

12. Nagaraja KV, Emery DA, Jordan KA, et al. Scanning electron microscopic studies of adverse effects of ammonia on tracheal tissues of turkeys. *Am J Vet Res* 1983;44:1530–1536.

13. Nagaraja KV, Emery DA, Jordan KA, et al. Effects of ammonia on the quantitative clearance of *Escherichia coli* from lungs, air sacs, and livers of turkeys aerosol vaccinated against *Escherichia coli*. *Am J Vet Res* 1984;45:392–395.

14. Anderson DP, Beard CW, Hanson RP. The adverse effects of ammonia on chickens including resistance to infection with Newcastle disease virus. *Avian Dis* 1964;8:369–379.

15. Osweiler GD, Carson TL, Buck WB, et al. Toxic gases. In: *Clinical and diagnostic veterinary toxicology*. 3rd ed. Dubuque, Iowa: Kendal/Hunt Publishing Co, 1985;369–371.

16. Luebs RE, Davis KP, Laag AEW. Diurnal fluctuation and movement of atmospheric ammonia and related gases from dairies. *J Environ Qual* 1974;3:265–269.

17. Loehr RC. Animal waste management—problems and guidelines for solutions. *J Environ Qual* 1972;1:71–78.

18. Hogsette JA. Fly control by composting manure at a south Florida equine facility. In: RS Patterson, PG Koehler, PB Morgan, et al, eds. *Status of biological control of filth flies*. Washington, DC: US Government Printing Office, 1981;105–113.

19. Boire S, Bay DE, Olson JK. An evaluation of various types of manure and vegetative material as larval breeding media for the stable fly. *Southwest Entomol* 1988;13(4):247–249.

20. English RV, Nasisse MP. Ocular parasites. In: Smith BP, ed. *Large animal internal medicine*. Philadelphia: CV Mosby Co, 1990; 1245–1246.

21. Barnett KC, Crispin SM, Lavach JD, et al. *Equine color atlas and text of equine ophthalmology*. London: Mosby-Wolfe, 1995;90.

22. Dougherty CT, Knapp FW, Burrus PB, et al. Behavior of grazing cattle exposed to small populations of stable flies (*Stomoxys calcitrans* L). *Appl Anim Behav Sci* 1995;42:231–248.

23. Schmidtmann ET. Face flies, *Musca autumnalis*, and ear flap behavior in Holstein cows. *J Agric Entomol* 1985;2:69–72.

24. Okumura T. The relationship of attacking fly abundance to behavioral responses of grazing cattle. *Jpn J Appl Entomol Zool* 1977; 21:119–122.

25. Harvey TL, Launchbaugh JL. Effect of horn flies on behavior of cattle. *J Econ Entomol* 1982;75:25–27.

26. Turner EC, Ruszler PL. A quick and simple quantitative method to monitor house fly population in caged layer houses. *Poult Sci* 1989;68:833–835.

27. Axtell RC. *Fly control in confined livestock and poultry production*. Technical monograph. Greensboro, NC: Ciba-Geigy, 1986; 16.

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Effect of daily floor treatment with sodium bisulfate on the fly population of horse stalls

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Objective—To determine application rate and effectiveness of sodium bisulfate to decrease the fly population in a horse barn environment.

Sample Population—12 privately owned farms in southeastern Pennsylvania.

Procedure—Application rates of sodium bisulfate were approximately 2.3 kg/stall, 1.1 kg/stall, and 0.5 kg/stall. Two or 3 stalls were treated, and 1 or 2 stalls were not treated (control stalls) at each farm. Farm personnel applied sodium bisulfate in treated stalls daily for 7 days. Fly tapes were hung from the same site in treated and control stalls. After 24 hours, the fly tape was removed, flies adhering to the sticky surface were counted and recorded, and a new fly tape was hung. This procedure was repeated daily during each of the testing periods.

Results—Following the application of 2.3 kg of sodium bisulfate/stall, the numbers of flies collected on the fly tape were significantly decreased in treated stalls, compared with control stalls during the same time periods on 9 of the 12 farms evaluated. Following the application of 1.1 kg of sodium bisulfate/stall, fly numbers were significantly decreased in treated stalls on 6 of the 9 farms evaluated. Following the application of 0.5 kg of sodium bisulfate/stall, fly numbers were significantly decreased in the treated stalls on 3 of the 4 farms evaluated.

Conclusions and Clinical Relevance—Our findings suggest that sodium bisulfate would be effective for fly control in horse barns. (*Am J Vet Res* 2000; 61:910–913)

Volatilization of ammonia has been attributed to microbial decomposition of nitrogenous compounds,[1,2] principally urea, in equine manure. Manure pH has a decisive role in ammonia volatilization[3]; ammonia release is small when manure pH is < 7.0 but substantial when pH is > 8.0. Acidification has proven to be an efficient method of reducing ammonia losses in cattle slurry.[4] Sodium bisulfate, a dry acid similar in size and consistency to coarse salt crystals, is used to reduce ammonia concentration[3] and provide an environment in which bacteria cannot grow by lowering the pH in poultry litter. Sodium bisulfate (2.3 or 4.5 kg/9.3 mm^2) applied to a horse stall environment daily decreases ammonia concentration, manure pH, and number of flies in the stall environment, compared with a control period without sodium bisulfate.[3] Flyevasive behavior patterns of ponies occupying the stalls including tail swishes, head tosses, and kicking or striking, are decreased during the period of sodium bisulfate application.[3]

Results of studies indicate that equine facilities are suitable habitats for large-scale breeding of stable flies and houseflies.[6] Mean stable fly pupae production and weight is greatest in horse manure, compared with cattle, swine, and chicken manure.[7] Flies are a nuisance to horses and people working with horses. The feeding activity of face flies induces ocular lacrimation, damages conjunctival tissues, and may expose horses to fly-borne pathogens. Flies are vectors for the parasites *Habronema* and *Onchocera* spp[8,9] and have been associated with nonspecific and eosinophilic conjunctivitis. The purpose of the study reported here was to determine application rate and effectiveness of sodium bisulfate[a] to decrease the fly population in a horse barn environment.

Materials and Methods

Farms—Twelve privately owned farms in southeastern Pennsylvania were used for test sites. The farms were chosen on the basis of their accessibility and the willingness of farm personnel to record data. Age of the barns ranged from 2 to 140 years (mean – SD, 52.7 – 43.5 years). Barns were built of wood, cinder block, stone, or some combination of these materials. Flooring materials in the stalls were rubber mats (n = 7), dirt (3), stone dust (1), or blacktop (1). Bedding materials were wheat straw (n = 7), sawdust (4), or wood shavings (1). Three to 5 adjacent identically sized stalls housing horses at least 12 h/d were used in the study. Stall sizes varied from farm to farm with a range of 9.3 to 13.8 m^2. Although the manure handling procedure was the same for all stalls in a barn on each farm, procedures varied among farms. Bedding material was removed completely from stalls daily on 8 farms. Four farms picked up only fresh manure daily. Concurrent fly control methods were used on 8 farms and included chemical fly spray of stalls, fly attractant lights, or fly spray on horses on occasion. Experimental protocols were reviewed and approved by the Clinical Investigation Review Committee of the Department of Clinical Studies, New Bolton Center, University of Pennsylvania.

Application—Application rates of sodium bisulfate were approximately 2.3 kg/stall, 1.1 kg/stall, and 0.5 kg/stall. At 10 sites, 2 stalls were treated, and 2 stalls were not treated (control stalls). At 1 site, 2 stalls were treated, and 1 stall was not treated (control stall). At 1 site, 3 stalls were treated, and 2 stalls were not treated (control stalls). Farm personnel applied sodium bisulfate to treated stalls daily for 7 days.

Study design—The 12-week study was performed from June 18 through September 7, 1998 and was scheduled as follows. The first day of testing was between Jun 18 and Aug 7. The mean temperature during this period was 75.2 – 4.0 F (range, 53.1 to 93.3 F). All 12 farms first evaluated the 2.3-

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kg/stall application rate. Between 1 and 14 days following completion of the 2.3-kg/stall testing, 9 of the 12 farms began testing the 1.1 kg/stall application rate. Between 1 and 15 days following the completion of the 1.1 kg/stall testing, 4 of these 9 farms evaluated the 0.5 kg/stall application rate.

Fly evaluation—Fly tapes[b] were hung from the same sites in each treated and control stall. Sites used were the ceiling of the center, front, or rear portion of the stall. Twenty-four hours later, the fly tape was removed, flies adhering to the sticky surface were counted and recorded, and a new fly tape was hung. This procedure was repeated daily during each of the testing periods.

Signs of toxicosis—Horses stabled in the study stalls were observed daily for skin lesions, signs of lameness, or abnormalities of appearance, actions, or attitude. Farm personnel who handled the sodium bisulfate were asked to report miscellaneous health problems and cutaneous lesions.

Statistical analyses—Because the number of flies in untreated stalls (ie, the background count) was not consistently associated with fly reduction attributable to treatment, mean daily and weekly counts of flies captured in each stall were determined. Inspection and preliminary analysis of data homogeneity suggested that determination of mean counts across replications would not lead to loss of information. For each farm, mean daily and weekly counts of flies associated with treated stalls and flies associated with untreated stalls were determined. Thus, data analysis was based on a data set containing the following variables: treatment, count of flies in treated stalls and untreated stalls, and farm identification.

To examine the likelihood of the outcome of the experiment being influenced by the temporal offset of the treatment applications, we fitted a model including time period and farm to the normalized background counts. If background count changed during the experiment, changes in fly numbers in treated stalls might otherwise be erroneously attributed to efficacy of treatments.

To compare efficacy of the 0.5-, 1.1-, and 2.3-kg/stall application rates, we used a Poisson regression model in which overdispersion was accommodated.[10] Rationale for use of this model was based on an application of Poisson regression by Clayton[11] in which the capacity of a new anticonvulsant drug to assist in the control of epilepsy was modeled. Components of our model included fly count (the dependent variable), background count as the exposure rate, treatment (as 2 indicator variables, with the 0.5-kg/stall application rate as the referent level), and farm (as 11 indicator variables). Differences were considered significant at $P < 0.05$.

Results

Fly evaluation—After application of 2.3 kg of sodium bisulfate/stall, numbers of flies collected daily and weekly on the fly tape were significantly decreased in treated stalls, compared with control stalls, during the same time periods on 9 of the 12 farms evaluated (Fig 1 and 2). After application of 1.1 kg of sodium bisulfate/stall, numbers of flies collected on the fly tape daily and weekly were significantly decreased in treated stalls, compared with control stalls, during the same time periods on 6 of the 9 farms evaluated. After application of 0.5 kg of sodium bisulfate/stall, numbers of flies collected on the fly tape daily and weekly were significantly decreased in treated stalls, compared with control stalls, during the same time periods on 3 of the 4 farms evaluated.

Changes in background count were not significantly associated with time of experiment. Fly numbers in any individual stall, either treated or control, were similar regardless of day of treatment. Magnitude of decrease in fly numbers in treated stalls was not different between the 2.3- and 1.1-kg/stall application rates. Decrease in fly numbers in the 0.5-kg treated stalls was significantly less than that in the 2.3-kg and 1.1-kg treated stalls.

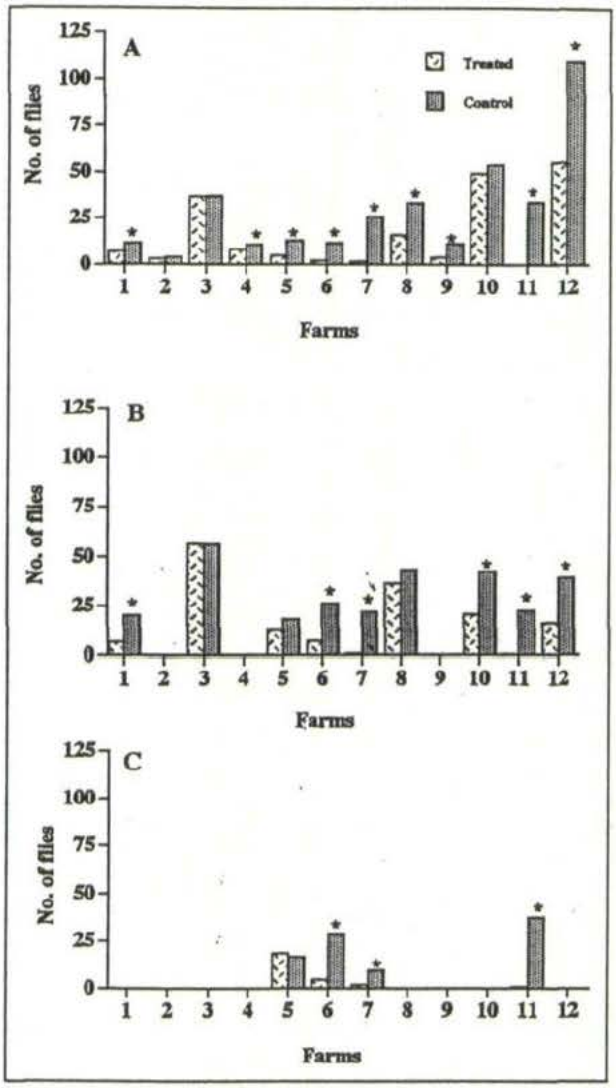

Figure 1—Mean daily fly counts in stalls treated with 2.3 kg (A), 1.1 kg (B), or 0.5 kg (C) of sodium bisulfate and untreated (control) stalls on 12 horse farms. *Significant ($P < 0.05$) difference between groups.

The overall model was significant ($P = 0.01$), and the admission of over-dispersion was judged to be warranted ($P = 0.01$). Dispersion of the final model was approximately 0.4. Incidence rate ratios for the 1.1- and 2.3-kg application rates, compared with the 0.5-kg rate, were significantly lowered (ie, reduction in fly count for the 1.1- and 2.3-kg rates was significant, compared with the 0.5-kg rate). The incidence rate ratio for 1.1-kg rate versus the 0.5-kg rate was 0.61 − 0.10 and for the 2.3-kg rate versus the 0.5-kg rate was 0.60 − 0.10. A difference between effects of the 1.1-kg and 2.3-kg application rates was not detected. In a practical sense, this means that approximately 40% fewer flies per day were in the 1.1- and 2.3-kg treated stalls than in the 0.5-kg treated stalls. The incidence rate ratio for 0.5-kg appli-

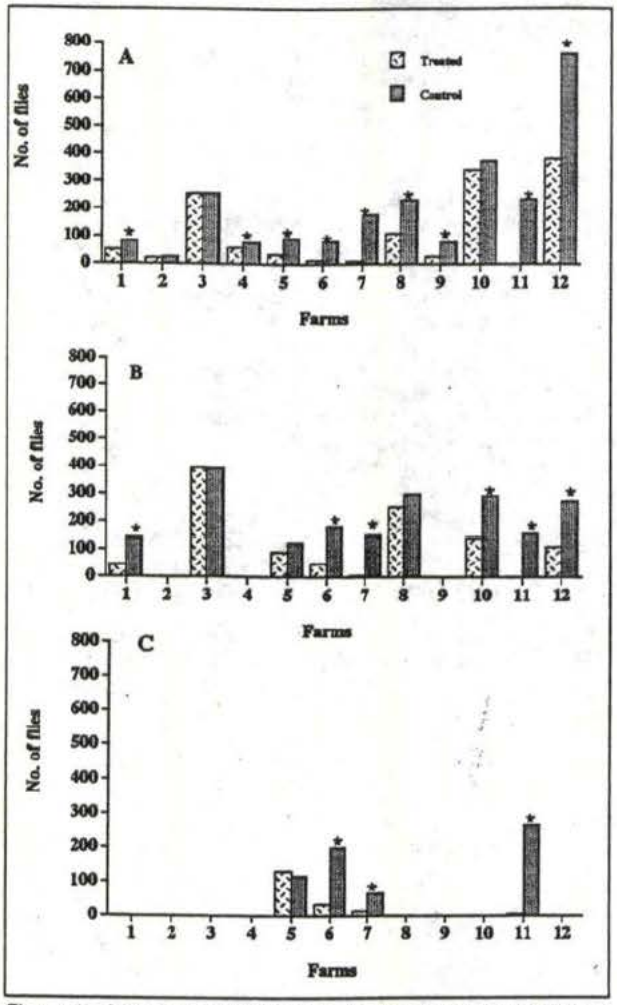

Figure 2—Mean weekly fly counts in stalls treated with 2.3 kg (A), 1.1 kg (B), or 0.5 kg (C) of sodium bisulfate and untreated (control) stalls on 12 horse farms. *Significant ($P < 0.05$) difference between groups.

cation rate versus background count was 0.21; that is, application of 0.5 kg sodium bisulfate suppressed fly counts by approximately 79%.

Different patterns of response amongst the farms was also detected. Three farms (No. 6, 7, and 11) sustained the best fly control with incidence rate ratios ranging from 0.02 to 0.40, compared with the reference farm (No. 1). Six farms (No. 2, 4, 5, 8, 9, 10, and 12) achieved approximately the same level of control as the reference farm, and 1 farm (No. 3) sustained the lowest level of fly control, with incidence rate ratios 3 times higher than those of the reference farm.

Signs of toxicosis—No signs of cutaneous lesions, lameness, or any other health problems were evident in horses stabled in the treated stalls during the study. Signs of cutaneous lesions or other health problems were not evident among personnel handling the sodium bisulfate during the study.

Discussion

The study reported here was designed so that each barn served as its own control, preventing differences in barn setting, floor or bedding material, and stall cleaning procedures from influencing evaluation of the effect of sodium bisulfate. Pairing treated and control stalls and evaluating them during the same time period eliminated the effect of season and weather on the fly population, because the control period and treated period were concurrent.

Many methods are used to monitor fly populations in the environment, including sticky fly tape, spot card, baited jug trap, grill count, and subjective visual index.[12] Sticky tape provides a simple quantitative method to monitor flies in a horse barn environment and is commonly used in commercial and recreational horse barns to control flies. Sticky fly tape was effective in a previous study[3] that monitored fly counts in horse stalls. Our study did not determine the types of flies attracted to the sticky fly tape.

Development of housefly larvae is dependent on manure pH and temperature; manure pH 2 is considered toxic to housefly larvae and prevents their development.[6] Sodium bisulfate decreases manure pH and likely prevented flies from hatching in manure in the stalls of our study. Larval development time at an environmental temperature of 35 C (95 F) or 20 C (68 F) ranges from 9 to 22 days or 6 to 8 days, respectively.[13] Although the decrease in fly numbers during the period of treatment may have been attributable to decreased larval development secondary to low manure pH, this theory would not account for the decreased fly numbers detected in treated stalls within 24 hours of application of sodium bisulfate. The authors speculate that the change in manure pH made the manure less attractive as a breeding site to adult flies already in the area.

The explanation for sodium bisulfate's lack of effectiveness in reducing fly numbers on certain farms using a particular application rate was not readily apparent. Mean weekly fly counts and mean daily fly counts in control stalls on these farms ranged from 26.5 to 765 and 3.8 to 109.3, respectively.

The effect of sodium bisulfate in decreasing fly counts in treated stalls was detectable on the first day of treatment and persisted at the same level throughout the week, suggesting that the change in the environment made the stalls immediately less appealing to the flies. A previous study[3] has documented the effect of sodium bisulfate on lowering the pH of horse manure and decreasing ammonia concentrations in stalls. It seems likely that the effect on pH or ammonia concentration is responsible for the stalls' decreased appeal to flies. Although it may be recommended that application be performed daily or every other day, the immediate effect detected in the study reported here suggests that treatment may be used as needed, because cumulative effect is not necessary to achieve decreased fly counts.

Results indicated that the highest application rate (2.3 kg/stall) had no advantage over the moderate application rate (1.1 kg/stall). Although results did suggest that the decrease in fly counts was not as great with the lowest application rate (0.5 kg/stall), sodium bisulfate remained effective on 3 of the 4 farms in which stalls were treated with that chemical concentration. To have the greatest effect, an application rate

of 1.1 kg/stall is recommended, although application at 0.5 kg/stall remains effective. The authors recommend that application be performed initially on a daily basis and continued as needed.

At no time during the study were there indications of adverse effects in horses stabled in treated stalls or farm personnel handling the sodium bisulfate. Safety issues were not expected, because sodium bisulfate is accepted as safe and can be used in food.[d]

[a]ComfortZone, Jones-Hamilton Co, Walbridge, Ohio.
[b]TAT fly paper, Walco-Linck Co, Valley Cottage, NY.
[c]Pitts C, Pennsylvania State University, Philadelphia, Penn: Personal communication, 1995.
[d]Food Chemical Codex, 4th ed, 1997, Washington, DC: National Academy Press.

References

1. Burnett WE, Dondero NC. Microbiological and chemical changes in poultry manure associated with decomposition and odor generation, in *Proceedings*. Cornell University Conf Agricultural Waste Manage 1969;271–291.
2. Carlile F. Ammonia in poultry houses: a literature review. *Worlds Poult Sci J* 1984;40:99–113.
3. Ivos J, Asaj A, Marjanovic LJ, et al. A contribution to the hygiene of deep litter in the chicken house. *Poult Sci* 1966;45:676–683.
4. Bussink DW, Huijsmans JFM, Ketelaars JJMH. Ammonia volatilization from nitric-treated cattle slurry surface applied to grassland. *Neth J Agric Sci* 1994;42:293–309.
5. Sweeney CR, McDonnell S, Russell G, et al. Effect of sodium bisulfate on ammonia concentration, fly population, and manure pH in a horse barn. *Am J Vet Res* 1996;57:1795–1798.
6. Hogsette JA. Fly control by composting manure at a south Florida equine facility. In: Patterson RS, Koehler PG, Morgan PB, et al, eds. *Status of biological control of filth flies*. Washington, DC: US Government Printing Office, 1981;105–113.
7. Boire S, Bay DE, Olson JK. An evaluation of various types of manure and vegetative material as larval breeding media for the stable fly. *Southwest Entomol* 1988;13:247–249.
8. English RV, Nasisse MP. Ocular parasites. In: Smith BP, ed. *Large animal internal medicine*. St Louis: CV Mosby Co, 1990;1245–1246.
9. Barnett KC, Crispin SM, Lavach JD, et al. *Equine color atlas and text of equine ophthalmology*. London: Mosby-Wolfe, 1995;90.
10. Lindsey JK. *Modeling frequency and count data*. Oxford, England: Clarendon Press, 1997;156–158.
11. Clayton D. Poisson regression with a random effect. In: *Stata technical bulletin*. College Station, Tex: Stata Corp, 1998: 30–33.
12. Turner EC, Ruszler PL. A quick and simple quantitative method to monitor house fly population in caged layer houses. *Poult Sci* 1989;68:833–835.
13. Axtell RC. *Fly control in confined livestock and poultry production*. Greensboro, NC: Ciba-Geigy;1986:16.

BPPD PRAT ACTION CODING FORM

PM 90: Janet Andersen

REGISTRANT/COMPANY NAME:

Technology Sciences Group Inc.

EPA REG./FILE SYMBOL 33907-E

ACTION CODE 161

(New A.I/EUP'S/Tolerances: Yes☐ No☐)

DATE OF APPLICATION 10/11/01

EPA RECEIVED DATE 10/12/01

BPPD RECEIVED DATE 10/19/01

SUBMISSION BARCODE S605521

ASSIGNED IN PRAT: Yes☒ No☐

COMPLETED BY T. Bethea DATE 10/26/01

LOGGED IN BRATS: Yes☑ No☐ DATE 10/31/01 COMPLETED BY CP

RAL RECEIVED CP (RAL initials) DATE 10/31/01

Fast Track: Yes☑ No☒

Reviewer Fast Team ① Diana H ② Carole P.

Assigned by CAH 10/31/01 odh

[*Note: If Fast Track, you may need to change Reviewer's Name in PRAT.*]

86-5 Dress?

FINAL ACTION

RESPONSE CODE: 11

RESPONSE DATE: 11/9/01

MOS: _____ (1) Cite All
_____ (4) Not Applicable
_____ (8) Selective

CRP	Yes☐	No☐
Restricted Use:	Yes☐	No☐
Manufacturing Use:	Yes☐	No☐
Exclusive Use:	Yes☐	No☐

Technology Sciences Group Inc.
Arizona: Regulatory Division
4061 North 156th Drive
Goodyear, AZ 85338
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E-Mail: jazkatz@qwest.net

Iain Weatherston, Ph.D.
Senior Regulatory Consultant
Pesticide Division

June 19, 2003

Driss Benmhend
Biopesticide and Pollution Prevention Division
Biochemicals Branch
Office of Pesticide Programs
U.S. Environmental Protection Agency
Crystal Mall Building #2, 9th Floor
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Driss:
Following up on the action items from the May 7th meeting to discuss and resolve the issues with the Comfort Zone registration application and to expedite approval please find the following:

1] To respond to Agency concerns over exposure to dust since the product is Toxicity Category I based on eye irritation, the exposure being both to the animals and also to humans (workers, horse owners, children) a statement has been added to the label that horses should be removed from the stall while the Comfort Zone is being applied, and further details of the sodium bisulfate beads (sample are provided at may 7th meeting) are provided to indicate that the product as produced is dust free, and is of such a hardness that shipping and handling will not cause the beads to break and form a dust.
A detailed description of the manufacturing method the sodium bisulfate granular beads (MRID 45516001; page 3 of the confidential attachment,) including a flow diagram (pages 8 and 9 of the confidential attachment) shows that the final step in the production scheme where the molten sodium bisulfate is sprayed inside the top of a vertical spray chamber to produce the spherical beads approximately 0.75 mm in diameter. The cooled beads are then passed through a 40-mesh sieve to remove small particles and dust to ensure a dust free product.
The hardness of materials is measured by a relative scale of hardness called the Moh's Scale. The Moh's scale was devised by the German geologist Friedrich Moh in 1812 and has been a valuable aid to identifying minerals ever since. Here are the ten standard minerals in the scale.

1. Talc
2. Gypsum
3. Calcite
4. Fluorite
5. Apatite
6. Feldspar
7. Quartz
8. Topaz
9. Corundum
10. Diamond

The Moh's scale is strictly a relative scale. In terms of absolute hardness, diamond (hardness 10) actually is 4 times harder than corundum (hardness 9) and 6 times harder than topaz (hardness 8). Because it isn't made for that kind of precision, the Moh's scale uses half-numbers for in-between hardnesses. Dolomite, which scratches calcite but not fluorite, has a Moh's hardness of 3½ or 3.5. On the Moh's scale the hardness of the Comfort Zone beads are rated at 4 and are hence unlikely to produce dust or other fine particles on handling or shipment. There are a few

Manufacturing process information may be entitled to confidential treatment

handy objects that also fit in this scale. A fingernail is 2½, a penny is 3, a knife blade is 5½, glass is 5½, and a steel file is 6½.
Sodium bisulfate is also known to be hygroscopic (e.g. Merck Index, 9th Edition page 1109; [redacted] is soluble in 2 parts of cold water, and in 1 part of boiling water.) and rapidly absorbs water from the air and its surrounding. On application to the floor of the stall and to the bedding materials, the granular beads will begin to absorb water and dissolve, again eliminating the possibility of dust exposure to the eyes of humans or animals.

2] Attached to this letter is an updated version of the draft Comfort Zone label, this label now conforms to the discussions at the May 7th meeting, comments by Linda Hollis, and the Warranty Statement has been revised along the lines of one provided by Ms. Hollis. The warranty statement has been reviewed and approved as suitable for the Comfort Zone label by the Jones Hamilton attorneys.

Changes made to label and reflected in this iteration are:

a] All mention of trailers has been removed from the label. This was done at the request of Jones-Hamilton.
b] Above the detailed use instructions, in the Directions for Use section of the label a capitalized statement has been added as a result of the meeting discussions. This statement says, REMOVE HORSES FROM STALLS WHILE APPLYING COMFORT ZONE®
c] As per the meeting discussion no REI statement is required.
d] As per the meeting discussion, no separate PPE statement is required, Dr Reilly concurred that the "Wear goggles or face shield and rubber gloves when handling" statement is properly placed in the precautionary statement immediately under the signal word DANGER.
e] In the Directions for Use section the statement "The active ingredient of COMFORT ZONE® is approved by FDA as a general purpose feed additive for animal feeds" has been removed as a result of the meeting discussions since BPPD staffers considered it irrelevant to a pesticide label.

Driss, this information and the new draft label have resulted from the action items assigned to Jones-Hamilton at the May 7th meeting. If you have any questions or need further information please do not hesitate to contact me. The May 7th meeting I think resolved all of the outstanding issues and I look forward to receiving an approval soon.

Sincerely

Iain Weatherston

attachment: draft label

cc: (w/o)
Carl Knueven [Jones-Hamilton]
Bernie Murphy [Jones-Hamilton]
Ed Johnson [TSG - Washington]

PHYSICAL/CHEMICAL CHARACTERISTICS
[Guideline 151-17]

SOLUBILITY:	Water [cold] 28.6 g/100g @ 25°C Water [hot] 100g/100g Alcohol - slightly soluble Non polar organic solvents - insoluble
VAPOR PRESSURE	Not applicable to manufacturing use or end-use products [See Table 2 in OPPTS 830.1000].
FLAMMABILITY	Not required. These data are only required if the product contains a combustible liquid [See Footnote 6 to Table at 40 CFR 158.190, page 93 in July 2000 edition of CFR Title 40]
EXPLODABILITY	Not required. These data are only required if the product is potentially explosive [See Footnote 7 to Table at 40 CFR 158.190, page 93 in July 2000 edition of CFR Title 40]

Procedure #: JH/W-461-QC		Page 1 of 2
Title:	ACIDITY AND ASSAY DETERMINATION	Issue Date: 3/6/96
	OF SODIUM BISULFATE	Rev. #: 1

ACIDITY AND ASSAY DETERMINATION OF SODIUM BISULFATE

PURPOSE

This procedure documents the steps required to determine the acidity (as % H_2SO_4) of sodium bisulfate by titration. From this acidity value, the material assay (as % $NaHSO_4$), the % Na_2SO_4, and the free sulfuric acid (if present) can be calculated.

RESPONSIBILITY

This procedure is routinely used by Shift Leaders, Operators, Loaders, and Quality Control personnel for monitoring the process and certifying end product.

RESOURCES

The following materials are required to perform this procedure:

Beaker, 100 ml buret, magnetic stirrer and stir bar, top loading balance (with readability of 0.01 g), 1 N sodium hydroxide, Phenolphthalein indicator, water, calculator.

GENERAL HYGIENE AND SAFETY

The following personal protective equipment must be worn when performing this procedure:

Safety glasses

PROCEDURE

1 Add approximately 100 mls of water to a clean beaker.

2 Add a 3.00 g sample of sodium bisulfate into the water, either with a weighing boat or by taring the beaker on the balance and adding the SBS directly to the water.

3 Transfer sodium bisulfate to the beaker, and add 3 to 5 drops of phenolphthalein indicator and stir bar.

QC/Environmental Coordinator:	Date: 3/6/96

Procedure #: JH/W-461-QC		Page 2 of 2
Title:	ACIDITY AND ASSAY DETERMINATION	Issue Date: 3/6/96
	OF SODIUM BISULFATE	Rev. #: 1

4 Place the beaker on the magnetic stirrer and dissolve the sodium bisulfate. The mixture should be clear.

5 Fill the buret with 1 N sodium hydroxide using the gravity feed system. This will standardize the buret volume to 0 and send any residual sodium hydroxide to the drain.

6 Add sodium hydroxide to the beaker slowly until a pink or purple end point appears and remains.

7 Note the final level of sodium hydroxide in the buret to the nearest 0.1 ml.

8 Determine the % H_2SO_4 by reading from the Titration Chart or by calculating using the following formula:

$$\% H_2SO_4 = \frac{\text{mls of NaOH x N NaOH x 4.904}}{\text{weight of sample in grams}}$$

9 Determine the % $NaHSO_4$ by reading from the Titration chart or by calculating using the following formula:

$$\% NaHSO_4 = \% H_2SO_4 \times 2.448$$

10 If the % $NaHSO_4$ is equal to 99.7% (100% less 0.3% for moisture), there is no free sulfuric acid or Na_2SO_4 present.

11 If the % $NaHSO_4$ is less than 99.7% (100% less 0.3% for moisture), the remaining material is % Na_2SO_4 and is calculated the following way:

$$\% Na_2SO_4 = 99.7\% - \% NaHSO_4$$

12 If the % $NaHSO_4$ is greater than 99.7% (100% less 0.3% for moisture), there is free sulfuric acid available. This free sulfuric acid is calculated by the following:

$$\text{Free } \% H_2SO_4 = \frac{\% NaHSO_4 - 99.7\%}{2.448}$$

QUALITY RECORDS

None

SBS ANALYSIS

Lot No.	A191X1
Acidity as % H_2SO_4	38.4
Assay as % $NaHSO_4$	94.0
Moisture as % H_2O	< 0.4
% as Insolubles	< 0.05
% as Iron	< 0.01

Screen Test (Cumulative %)

+	10	Mesh	0.00
+	20	Mesh	37.75
+	40	Mesh	99.07
+	60	Mesh	99.98
+	100	Mesh	99.99
-	100	Mesh	100.00
		Lost	0.00

Tested by Joel F. Jurgen Date 1/22/2001

SBS ANALYSIS

Lot No.	B021X4
Acidity as % H_2SO_4	37.9
Assay as % $NaHSO_4$	92.8
Moisture as % H_2O	< 0.4
% as Insolubles	< 0.05
% as Iron	< 0.01

Screen Test (Cumulative %)

+	10	Mesh	0.00
+	20	Mesh	48.09
+	40	Mesh	99.81
+	60	Mesh	100.00
+	100	Mesh	100.00
-	100	Mesh	100.00
		Lost	0.00

Tested by Joel F. Lange Date 2/09/2001

SBS ANALYSIS

Lot No.	C221X1
Acidity as % H_2SO_4	38.6
Assay as % $NaHSO_4$	94.5
Moisture as % H_2O	< 0.4
% as Insolubles	< 0.05
% as Iron	< 0.01

Screen Test (Cumulative %)

+	10	Mesh	0.00
+	20	Mesh	32.51
+	40	Mesh	99.33
+	60	Mesh	99.99
+	100	Mesh	99.99
-	100	Mesh	100.00
		Lost	0.01

Tested by Joel F. Jaenga Date 3/05/2001

SBS ANALYSIS

Lot No.	H301X3
Acidity as % H_2SO_4	38.3
Assay as % $NaHSO_4$	93.8
Moisture as % H_2O	< 0.4
% as Insolubles	< 0.05
% as Iron	< 0.01

Screen Test (Cumulative %)

+	10	Mesh	0.00
+	20	Mesh	57.97
+	40	Mesh	99.03
+	60	Mesh	99.90
+	100	Mesh	99.98
-	100	Mesh	99.99
		Lost	0.01

Tested by Joel F. Jungo Date 9/04/2001

Manufacturing process information may be entitled to confidential treatment

MANUFACTURING PROCESS
[Guideline 151-11]

The process used by Jones-Hamilton Company to produce sodium bisulfate is a continuous process. A schematic of the process is given in the Appendix.

To produce sodium bisulfate, sodium chloride [NaCl] and sulfuric acid [H_2SO_4] are reacted continuously in a molten bath of sodium bisulfate at 600 - 630°F

$$NaCl + H_2SO_4 \rightarrow NaHSO_4 + Hcl$$

The sodium chloride is obtained from a food grade production facility [e.g. Morton Salt, a product data sheet is included in the Appendix]. The sulfuric acid is also a food grade product that comes from ore smelting operations [eg Dupont, a certificate of quality is included in the appendix]. A ratio of 0.636 lb of sodium chloride per 1 lb of sulfuric acid is fed continuously into the reactor. The produced hydrogen chloride is pulled from the reactor by a vacuum and taken to an absorber tower where it is absorbed into water to produce 32% hydrochloric acid.

The molten sodium bisulfate flows from the reactor to a holding tank [finishing pot] where water is added to reduce the temperature to 420°F. The molten sodium bisulfate is then pumped to a spray disk where it is sprayed out and cools as it falls in the air to form solid prills. The prills are conveyed, classified by screens and stored in above ground storage bins. From these bins it is loaded into rail cars, bulk trucks and packaged goods. Further details of the ISO 9002 procedures for the operation of the reactor are given in the Appendix. The materials used in the construction of the equipment used to produce the sodium bisulfate are stainless steel, carbon steel and other proprietary materials.

Production samples of sodium bisulfate are collected at regular intervals over a 24 hour period. The production from each 24 hour period constitutes a particular lot [with a specific lot number]. Analysis is performed on each lot. The analytical data from five lots are given elsewhere in this volume.

DISCUSSION OF THE FORMATION OF IMPURITIES
[151-12]

[redacted]

Morton Salt Product Data

Purex® and TFC Purex® Salts
Silver Springs, NY and Rittman, OH Plants

PDS No. 105.1
3/95

Description

Purex® Salt is food grade, unscreened granulated sodium chloride produced in the vacuum pan evaporating system from raw, untreated brine. The salt crystals are cubic in structure. There are no additives.

TFC Purex® Salt is prepared by treating Purex® Salt with a minute concentration of Yellow Prussiate of Soda (sodium ferrocyanide), a water-soluble anticaking agent used in accordance with 21CFR Sec. 172.490.

Yellow Prussiate of Soda, as an incidental, nonfunctional additive under 21 CFR Sec. 101.100 (a) (3), is exempt from label declaration on foods incorporating the salt.

Chemical Analysis

	Rittman		Silver Springs	
	Typical	Range	Typical	Range
[1]Sodium Chloride (%)	99.83	>99.7	99.8	>99.6
Calcium Sulfate (%)	0.13	<0.19	0.19	<0.4
Calcium Chloride (%)	0.03	<<0.06	0.00	<0.03
Magnesium Chloride (%)	0.01	<0.02	0.00	<0.04
Ca & Mg as Ca (ppm)	520	<850	570	<1400
Moisture (%)	-	<0.1	-	<0.1
Insolubles (ppm)	-	<50	-	<50
Copper (ppm)	0.1	<0.4	0.0	<0.1
Iron (ppm)				
Free	0.2	<0.8	0.9	<<2.0
[2]Complexed	1.1	<2.3	1.1	<2.3
[3]Sodium Ferrocyanide (ppm)	6	<13	6	<13

[1] By difference of impurities, moisture-free basis (ASTM procedures).
[2] Contributed by sodium ferrocyanide (18% Fe).
[3] Used in TFC Purex® Salt only.

Nutrient Content (per 100g)

Ash (g)	>99.9	Magnesium (mg)	2
Calcium (mg)	50	Potassium (mg)	3
Chloride (g)	60.5	Sodium (g)	39.2
Iodine (ug)	<100		

Other Plants

See PDS 105.2 (Manistee, MI), PDS 105.3 (Hutchinson, KS), and PDS 105.4 (Weeks, LA and Grand Saline, TX).

Physical Properties

Pour (loose) bulk density is 1.15- 1.25 g/ml (72 - 78 lbs/ft³).

Production is unscreened, receiving a coarse scalping of 10-14 mesh.

Sieve Analysis

U.S.S. Mesh	Opening Microns*	Percent Retained** Rittman Typical	Rittman Range	Silver Springs Typical	Silver Springs Range
20	850	Tr	<1	0	Tr
30	600	4	0 - 11	1	<5
40	425	46	27 - 65	26	12 - 40
50	300	38	22 - 54	38	19 - 57
70	210	11	1 - 19	26	13 - 39
100	150	1	<2	7	1 - 17
Pan	-	Tr	<2	2	<7
Mean Crystal Size (um)		430		360	
Mean Surface Area (cm²/g)		66		79	

**25,400 Microns (micrometers, um) per inch*
*** On individual sieves.*

Packaging

50 & 80 lb. multiwall, polyethylene-lined kraft paper bags.

Unit Dimensions Gross Wt (lb)	LxWxH (in)	Cube (ft³)	Palletized* Units	Gross Wt. (lb)	Cube (ft³)
50.5	24x13x3	0.5	49	2545	43
80.9	28x16x3.5	0.9	30	2497	46

**Includes 48" x 40" standard wood pallet, @ 70 lb.*

Commodity Codes

	Purex® Salt	TFC Purex® Salt
50 lb. Bags	1514	-
80 lb. Bags	1522	1518
Semi Bulk Bags	1570	1573
Bulk	1519	1517

09/18/2001 13:26 5139412607 DUPONT FT HILL PAGE 02/03

Fort Hill Plant
11215 Brower Road
North Bend, Ohio 45052
513-941-4121

The miracles of science

September 17, 2001

Jones Hamilton Co
Plant GBS
Rail Station
Toledo Stanley Yards
Toledo, OH 43480
Attn: Carl Knueven

PRODUCT:	98% Sulfuric Acid
DATE SHIPPED:	September 17, 2001
DUPONT ORDER NO:	DCFM17209A07
CUSTOMER ORDER NO:	D1-3
CONTAINER:	DuPont Tank Car GATX-8459
NET QUANTITY:	198645 Lbs

CERTIFICATE OF QUALITY

Listed below are the results of tests run on LOT NO 2001091628, from which you received a shipment in DuPont Tank Car GATX-8459. Meets specifications.

PROPERTY/UNIT	METHOD	SPECIFICATION	RESULT
Acid Strength (%)	S8300.325.01.GR	98.00 to 99.50	98.50
Iron (ppm)	S8300.316.01.GR	20.0 Maximum	8.0
Light Transmission (%)	S8300.316.06.GR	70 Minimum	93

Cecil Newhouse

Cecil Newhouse
Production Technician

Procedure #: JH/W-320-PC	Page
Title: REACTOR AND FURNACE OPERATION	Issue Date: 5/1/01
	Rev. #: 4

Reactor Operation

The three most important operating parameters in the reactors are salt flow, sulfuric acid flow, and reactor temperature.

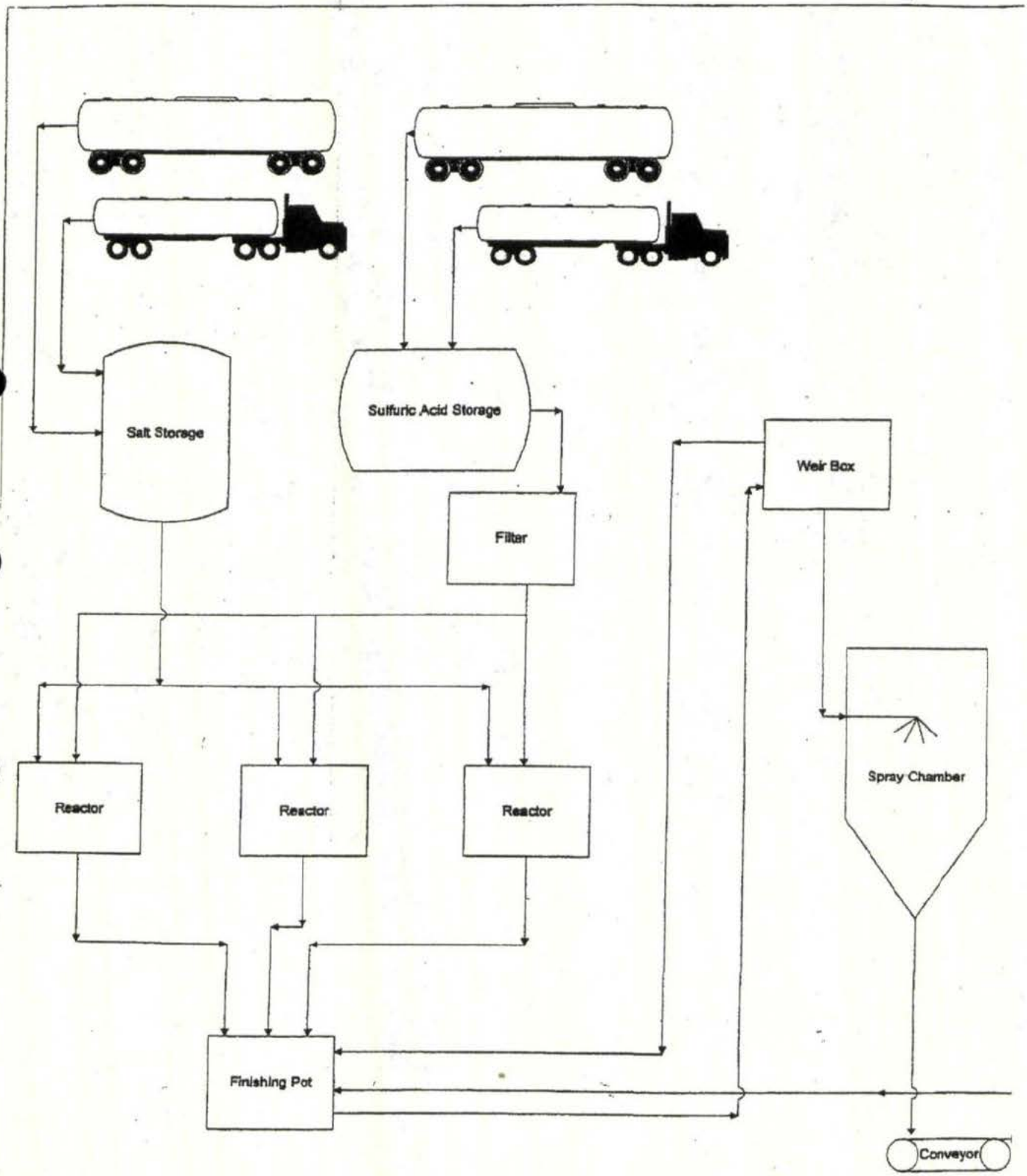
Salt and sulfuric acid are fed at controlled rates to the reactor which is enclosed in a gas-fired furnace. The sulfuric acid flow is maintained from the Control Room by a flow control system. The salt flow is regulated by rotary wheel feeders equipped with potentiometers which can be adjusted to a constant feed rate.

The salt and sulfuric acid flow rates into the reactors are adjusted to maintain the desired acidity. Due to the lack of consistent control of the salt flow and ease of control of sulfuric acid flow, the salt flow (as controlled by the potentiometer) is usually held constant while the sulfuric acid flow control is adjusted to maintain the desired acidity. The SBS melt that is created overflows from the individual reactors to the finishing pot (V-500).

Due to the generation of HCl gas in the reactor, a considerable amount of foam is generated on top of the melt. This makes it difficult to see the melt unless the raw material feeds are turned off.

Reactors 100, 200 and 300 are surrounded by a gas-fired furnace (H-100, 200, and 300) which is manually adjusted to control the reactor temperature at the desired point. Too low of temperature leads to incomplete reaction (residual HCl in the SBS) while excess temperature leads to the formation of pyrosulfates. The temperature in each furnace is monitored by a thermocouple suspended into the melt. Each furnace is equipped with 4 burners that are tangentially mounted to promote a circular motion of combustion gases around the reactor exterior, thus providing maximum heat transfer. The burners are manually turned on and off at different points to maintain the temperature in the reactor, while the furnace gases discharge through individual stacks monitored with thermocouples.

Reactor 400 is surrounded by a gas-fired furnace (H-400) containing five (5) radiant-tube elements. Each radiant tube has a gas-fired burner that burns inside of the tube, The tube is designed to radiate the heat of the burner to the reactor vessel. The temperature of the molten SBS is monitored by a thermocouple which automatically controls the five burners to maintain a temperature set by the operator. Each radiant tube has a recuperator that pre-heats the incoming combustion air with heat from the exiting combustion gases. The combustion gases of each tube exhaust to a main exhaust header that discharges to the atmosphere.


Salt Storage
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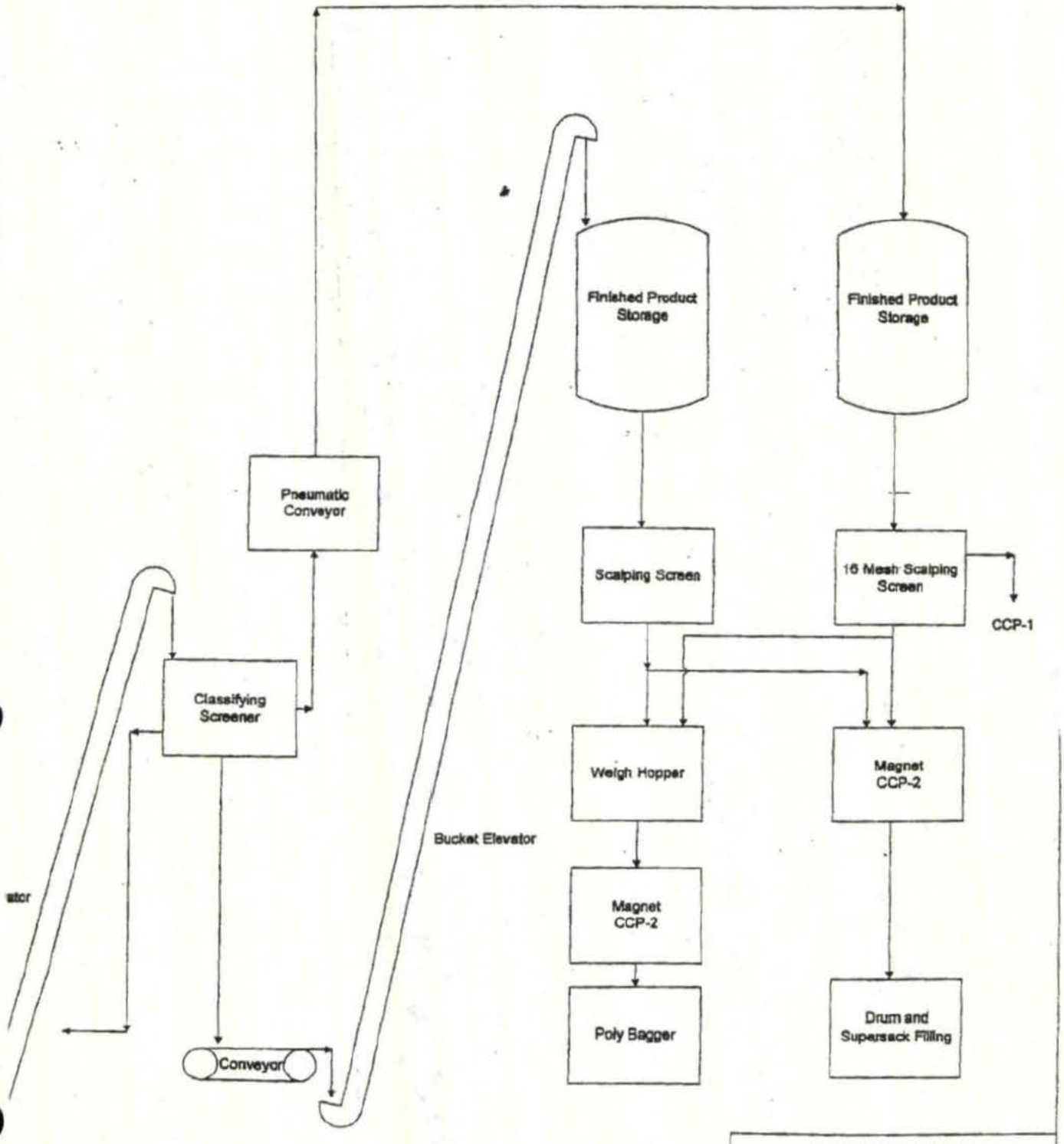
Spray Chamber
Finishing Pot
Conveyor


Finished Product Storage
Finished Product Storage
Pneumatic Conveyor
Scalping Screen
16 Mesh Scalping Screen
CCP-1
Classifying Screener
Weigh Hopper
Magnet CCP-2
Bucket Elevator
ator
Magnet CCP-2
Poly Bagger
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Wallbridge, Ohio
Block Flow Diagram - SBS Production

Inert ingredient information may be entitled to confidential treatment

ATTACHMENTS

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EFFECTIVE MANAGEMENT OF NUISANCE FLIES OF HORSES
IN MANURE, STABLES, HORSE BARNS, PADDOCKS AND HORSE TRAILERS

CONTROLS FLY POPULATIONS
MAKES BEDDING UNSUITABLE FOR FLY LARVAE
CONTROLS AMMONIA ODOR IN PADDOCKS AND MANURE PILES

ACTIVE INGREDIENT	
Sodium bisulfate [CAS# 7681-38-1]	93.2%
OTHER INGREDIENTS	6.8%
Total	100.0 %

KEEP OUT OF REACH OF CHILDREN

DANGER

CAUSES EYE & SKIN DAMAGE
HARMFUL IF SWALLOWED

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WAIVER REQUEST FOR SPECIFIC DATA REQUIREMENTS

ıte Oral Toxicity [151-10]

A waiver of the acute oral toxicity study is requested, based on:

i. its current widespread use in commerce in particularly in food processing and in animal feed additives .The material has GRAS status for use [a] as a pH control agent and leavening agent in cakes mixes at a level of 1 - 10 grams of sodium bisulfate per 1000 grams of total mix, and [b] as a pH control agent and processing aid in food at levels not to exceed good manufacturing practices. [GRAS Notice No. GRN 000003, a copy of which was submitted to BPPD in the original waiver request volume, Volume 33907-4].

ii. the fact that the Agency believes that the acute oral toxicity endpoint is 3,000 g/kg based on information in Dangerous Properties of Industrial Materials 7th Edition [N. I. Sax & R. J. Lewis, Sr 1989, p. 2770] Van Norstrand Reinhold, New York.

iii. the statement made in the 1992 letter from Bruce Sidwell [at that time Section 3 Chief in SRRD] to Jim Hill at CSMA [copy of which is included in Volume 33907-4) that an oral toxicity study [MRID 41622302] submitted by the Sodium Bisulfate Joint Venture and Jones-Hamilton that although the study was unacceptable but upgradable, but that upgrading it was not necessary since "the Agency is not currently requiring toxicology data on sodium bisulfate."

iv the Agency have previously decided in the reregistration process that all acute toxicity data for sodium bisulfate were waived or not required based on the extensive documentation provided in the literature on this chemical [footnote1 to the Acute Toxicity table on page 13 of the Mineral Acids RED.

NEW JERSEY

AGRICULTURAL EXPERIMENT STATIONS

BULLETIN NO. 292.

February 1, 1916.

The Response of The House-Fly (Musca domestica L). To Ammonia And Other Substances.*

By Charles H. Richardson, M.Sc., *Assistant Entomologist.*

In a recent article,[1] I have published results of some preliminary experiments on the response of the house-fly to ammonia and to manure extracts. From these experiments the following tentative conclusions were drawn; that ammonia possessed only a feeble attractiveness and that it was the fecal odor, probably due to skatol and indol which lured the female fly to the manure pile. The data were suggestive, but they lacked conclusiveness and it was decided to give the subject further consideration. Accordingly, more extended experiments were undertaken during the past summer and the results obtained form the basis of this paper.

*I wish to express my indebtedness to the following gentlemen: to Dr. T. J. Headlee, Entomologist of this Station for aid and encouragement throughout the course of these experiments; to Dr. F. E. Chidester, Department of Zoology, Rutgers College; Dr. R. G. Wright, Department of Chemistry, Rutgers College, and to Prof. A. W. Blair and Mr. H. C. McLean, Department of Soil Chemistry and Bacteriology of this Station, for help in a variety of ways.

1. 27th Ann. Rept. N. J. Agr. College Exp. Sta., 1914, p. 396-399.

It is now generally conceded that the house-fly lays its eggs most frequently in fermenting vegetable substances among which fermenting horse manure is generally shown preference.[2] Howard[3] has estimated that of the flies found about houses under city conditions more than 90 per cent come from horse stables or their vicinity.

In spite of the fact that manure often differs considerably, depending upon the character of the food, the age, and the health of the horse, its attractiveness to flies does not appear to vary with these conditions. Provided the manure is moist and has not suffered long exposure, it invariably attracts female house-flies if they are present in the vicinity. The flies come primarily to lay their eggs in the manure and although they may obtain some food from it this seems to be only a secondary object.

There is no doubt that the house-fly discriminates between fresh and old manure. Hutchison[4] was able to show in one experiment that a pile of horse manure which was moistened daily upon the exposed surface did not produce house-fly larvæ after the 12th day and that after the 5th day there was a sharp decline in the number of larvæ obtained. In other instances he found no eggs or larvæ, but only pupæ after eight and ten days.

I have carefully watched old manure compost throughout one entire fly-breeding season without finding a single house-fly larva or pupa.[5] During the past summer a series of experiments was conducted to determine how long after exposure small amounts of fresh horse manure would remain attractive to flies. Amounts ranging from one-third to one bushel were confined beneath cages for a certain period; then the cages were removed and after a day or more careful examination was made for eggs or small larvæ. In six experiments there was no oviposition after three, five, nine, ten and fifteen days. No attempt was made to keep the piles moist and

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2. Hewitt—The house-fly (*Musca domestica* L.), its structure, habits, development, relation to disease and control. Cambridge, England, 1914, p. 87-97.
3. The house-fly—disease carrier, New York, 1911, p. 7.
4. The migratory habit of house-fly larvæ as indicating a favorable remedial measure. An account of progress. Bull. U. S. Dept. Agr. No. 14, p. 8 and 9.
5. Loc. cit. p. 396 and 397.

a dry surface layer always formed, but this was not deeper, especially after three to five days exposure, than the depth which the house-fly often goes into fresh, moist manure to oviposit.

These studies suggested that something was present in the manure pile during the early stages of fermentation which allured the female house-fly and that this was lost or destroyed during later fermentation. It seemed highly probable that this attractive quality of fresh manure was due to the presence of one or several volatile chemical substances. Acting upon this hypothesis, the response of house-flies to a number of inorganic and organic compounds, which have been found in barnyard manures was observed.

Ammonia.

One of the most characteristic odors of fresh barnyard manure is that of ammonia. It it produced in considerable quantities from the urine with which manure is generally drenched and in smaller amounts as the result of the activities of microörganisms in the solid excrement. Wheeler[6] states that the liberation of ammonia from urea is completed in manure piles in from 4 to 5 days and that only small direct losses occur in the later stages of fermentation. In the solid excrement, the amount of ammonia produced is small, 1 per cent and 3 per cent of the total nitrogen content in one and six months respectively as Jentys and Dietzell have shown. (Wheeler loc. cit.)

Experiments With Ammonium Carbonate.

The ammonium carbonate (U. S. P.) used in these experiments contained approximately 97 per cent of ammonium acid carbonate and ammonium carbamate. It yielded about 31 per cent of ammonia gas.

Screen wire fly traps 9¾ inches high, 6 inches in diameter at the bottom and 4⅛ inches in diameter at the top were employed to catch the flies. Each trap was equipped at the base with a metal pan 5⅛ inches in diameter. There was a screen wire cone in the interior at the base with a hole in the apex large enough for a fly to pass into the trap.

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6. Manures and Fertilizers, New York, 1913, p. 45-47.

TABLE A.

No.	Material used in each trap	No. of traps	Duration of experim'ts	No. flies caught		Sex?
				Males	Females	
1a	170 gm. ammonium carbonate[1]	2	66 hrs.	1	27	
b	Control[2]	2	66 hrs.	0	0	3
2a	Ammonium carbonate remaining at conclusion of No. 1.	[3]2	51 hrs.	1	10	
b	Control	[3]2	51 hrs.	0	1	
3a	163 gm. ammonium carbonate + 50 c.c. water	2	97 hrs.	4	40	
b	Control 50 c.c. water	2	97 hrs.	3	0	
4a	Ammonium carbonate remaining at conclusion of No. 3.	[4]2	164 hrs.	1	9	2
b	Control	[4]2	164 hrs.	1	0	1
5a	113 gm. ammonium carbonate + 50 c.c. water	2	162 hrs.	0	9	
b	Control 50 c.c. water	2	162 hrs.	0	1	
6a	177 gm. ammonium carbonate + 50 c.c. water	2	147 hrs.	0	9	
b	Control 50 c.c. water	1	147 hrs.	0	0	
7a	234 gm. ammonium carbonate + 90 c.c. water	2	220 hrs.	2	21	
b	Control 90 c.c. water	1	220 hrs.	0	0	
8a	262 gm. ammonium carbonate + 50 c.c. water	[5]1	185 hrs.	1	2	
b	Control 50 c.c. water	1	185 hrs.	1	0	
9a	113 gm. ammonium carbonate. No water	2	77 hrs.	1	6	
b	113 gm. ammonium carbonate + 50 c.c. water	2	77 hrs.	4	27	1
c	Control—no water	1	77 hrs.	0	0	0
d	Control 50 c.c. water	1	77 hrs.	0	0	0
10a	85 gm. ammonium carbonate + 50 c.c. water	2	95 hrs.	1	25	
b	85 gm. ammonium carbonate.. No water	2	95 hrs.	0	1	
c	Control 50 c.c. water	1	95 hrs.	0	0	
d	Control—no water	1	95 hrs.	0	1	

Total number flies caught in 23 ammonium carbonate traps	205
Total number flies caught in 17 control traps	12
Total number of male flies in ammonium carbonate traps	16
Per cent of total	7.8
Total number of female flies in ammonium carbonate traps	186
Per cent of total	90.7

[1] Pans filled with water by rain storm.
[2] These traps were the controls in No. 1.
[3] These traps contained ammonium carbonate in No. 1.
[4] These traps were controls in No. 3.
[5] These traps contained ammonium carbonate in No. 3.
[6] Water added 94 hours after experiment was started.

The ammonium carbonate was placed in the pans in shallow glass dishes. The control traps also contained glass dishes. Water, although sometimes omitted, was generally added to the ammonium carbonate and control traps.

The traps were exposed long enough in most cases to completely volatilize the ammonium carbonate. This was hastened during clear weather by the sun's heat.

These experiments were conducted at a livery stable not far from a manure pit which was emptied once a week. The traps were placed on benches in linear series, each trap separated from its neighbors by several feet. The positions of ammonium carbonate and control traps were usually interchanged at the beginning of each new experiment. The results of ten experiments are given in Table A.

The ammonium carbonate traps caught 205 flies, the control traps 12. The presence of water in the former aided the escape of ammonia from the ammonium carbonate, because it prevented the formation of a white powdery surface layer. When this layer was allowed to form, fewer flies were caught and the pieces of dry ammonium carbonate gave a very feeble odor of ammonia. Controls which contained water did not have any apparent attractiveness to flies. It has long been known that flies will seek water, but the amount present in the controls, never more than 100 c.c., was apparently insufficient to induce flies to enter the traps. The water liberated from the breaking down of the ammonium carbonate was always so small in quantity that it could not have had any influence on the results.

Experiments were undertaken to demonstrate whether carbon dioxide, which is also a constituent of ammonium carbonate, possessed alluring qualities, but the results were negative. A single trap experiment with ammonium hydroxide gave results which further strengthened the belief that carbon dioxide was not necessary to bring forth a positive response from the house-fly.

A study of the sexes of flies caught in the ammonium carbonate traps showed that 90.7 per cent were females and 7.8 per cent males. Under ordinary conditions remote from breeding places the proportion of sexes is about equal with a slight excess of females.[7]

7. Hewitt loc. cit. p. 98.

This is equally true of flies bred from pupæ and those captured in the adult stage.

Since the traps were placed near a manure pit, which however was kept tightly closed and so dark that few flies entered, it was possible that a large percentage of flies present were females. If this were true traps baited with food materials would capture a predominance of females. Accordingly, traps baited with milk and in one instance with a sweet soda water were maintained in the close vicinity of the ammonium carbonate traps from July 21 till July 29. During this time 274 house-flies were captured 45.9 per cent of which were males and 54.0 per cent females. In the same period, the ammonium carbonate traps caught 65 flies, 7.6 per cent males and 89.2 per cent females. Food baits attracted nearly equal numbers of males and females; ammonium carbonate attracted a great preponderance of females.

Herms[8] has given data from a study of house-flies caught about manure piles and in houses which correspond very closely with the results from food baits and ammonium carbonate given above. Over 95 per cent of the house-flies caught in sweepings from a horse manure pile were females while only 57 per cent captured in a screened dwelling were of this sex. The great excess of females in the former locality was due to the fact that they had congregated there to oviposit.

These experiments show quite conclusively that the famale house-fly responds positively to the presence of ammonia gas in the amounts volatilized in these tests and that under the same conditions the response of the male fly is practically negative. The response is a true chematropism.

In all these experiments no instance was noted of the occurrence of house-flies' eggs in or upon the traps or on the dishes which held the ammonium carbonate. The odor of ammonia was sufficient to attract the female fly, but did not induce it to oviposit.

Experiments With Other Compounds.

During the summer, the following organic and inorganic compounds all of which have been found in barnyard manure were

8. The house-fly in its relation to public health. Bull. 215 Calif. Agr. Exp. Sta. 1911, p. 521 and 522.

tested: Skatol, indol, butyric acid, acetic acid, formic acid, valerianic acid, phenol, ethyl alcohol, hydrogen sulphide, ammonium sulphide, ammonium hydroxide and carbon dioxide. It was anticipated that skatol and indol would strongly attract the house-fly because of their persistent fecal odors and particularly because Howlett[9] has witnessed a species of *Sarcophaga* deposit larvæ in a flask containing a solution of skatol. Furthermore my own experiments with alcoholic, ether and aqueous extracts of horse manure led me to believe that one or both of these compounds might be responsible for the positive reaction of the female fly to horse manure.[10]

Of the other compounds Howlett[11] has found that valerianic acid attracted *Stomoxys calcitrans* L. and that valerianic and butyric acids had an attraction for an ortalid fly. In addition Barrows[12] has shown that acetic acid and ethyl alcohol call forth positive responses from *Drosophila*.

These experiments were conducted in a manner already described. (See ammonium carbonate experiments). The fluids exposed in traps were always placed in glass dishes. The carbon dioxide experiments however were performed in a different manner.

Each trap was equipped with an Erlenmeyer flask dropper which delivered hydrochloric acid, drop by drop, upon bits of limestone in the pan of the trap. By this method a small but fairly constant amount of carbon dioxide was evolved throughout a number of hours. A trap similarly equipped was used in the ammonium hydroxide experiment.

The results of these experiments are given in Table B.

Ethyl alcoholic solutions of skatol and indol used separately and combined in equal parts showed no marked attractiveness. Further experiments with skatol were interrupted because of a lack of material due to conditions in Europe. There appeared to be no difference in the attractive qualities of these compounds before and after the alcohol evaporated. Even in 0.1 per cent dilutions, a nauseous fecal-like odor was perceptible throughout the period of exposure at

9. The effect of oil of citronella on two species of *Dacus*. Trans. Ent. Soc. London, 1912, p. 416.
10. 27th Ann. Rept. N. J. Agr. College Exp. Sta., 1914, loc. cit.
11. Loc. cit.
12. The reaction of the pomace-fly, *Drosophila ampelophila* Loew to odorous substances. Jour. Exp. Zool. Vol. 4, No. 4, p. 515-537 (3 figures).

TABLE B.

No.	No. of traps	Material	Amount used in each trap	Duration of expt.	No. of flies captured
1a	2	Absolute ethyl alcohol (control)	10 c.c.	28 hrs.	1
b	2	0.1% absolute ethyl alcoholic solution of skatol	10 c.c.	28 hrs.	2
c	2	0.1% absolute ethyl alcoholic solution of indol	10 c.c.	28 hrs.	1
d	2	0.1% ethyl alcoholic solution of skatol and indol mixed	5 c.c. of each	28 hrs.	0
2a	2	Absolute ethyl alcohol (control)	10 c.c.	24 hrs.	1
b	2	0.3% absolute ethyl alcoholic solution of skatol	10 c.c.	24 hrs.	2
c	2	0.3% absolute ethyl alcoholic solution of indol	10 c.c.	24 hrs.	1
d	1	0.3% ethyl alcoholic solution of skatol and indol mixed	5 c.c. of each	24 hrs.	0
3a	2	Absolute ethyl alcohol (control)	10 c.c.	24 hrs.	0
b	2	0.3% absolute ethyl alcoholic solution of skatol	10 c.c.	24 hrs.	1
c	2	0.3% absolute ethyl alcoholic solution of indol	10 c.c.	24 hrs.	1
d	2	0.3% ethyl alcoholic solution of skatol and indol mixed	5 c. c. of each	24 hrs.	2
4a	1	1% absolute ethyl alcoholic solution of indol	20 c.c.	95 hrs.	0
b	1	Absolute ethyl alcohol (control)	20 c.c.	95 hrs.	0
5a	1	Absolute butyric acid	5 c.c.	99 hrs.	0
b	1	Distilled water (control)	5 c.c.	99 hrs.	0
6a	1	Glacial acetic acid	50 c.c.	120 hrs.	0
b	1	Distilled water (control)	50 c.c.	120 hrs.	0
c	1	Distilled Water	50 c.c.		
		Ammonium carbonate	85 gm.	120 hrs.	4 females
7a	1	Formic acid 90%	50 c.c.	71 hrs.	0
b	1	Distilled water (control)	50 c.c.	71 hrs.	0
c	1	Ammonium carbonate	85 gm.		
		Distilled water	50 c.c.	71 hrs.	4 females
8a	1	Butyric acid absolute Acetic acid 99% Formic acid 90%	5 c.c. of each	49 hrs.	0
b	1	Distilled water (control)	15 c.c.	49 hrs.	0
9a	1	Valerianic acid	50 c.c.	67 hrs.	0
b	1	Distilled water (control)	50 c.c.	67 hrs.	0
c	1	Ammonium carbonate	85 gms.		
		Distilled water	50 c.c.	67 hrs.	2 females

TABLE B—(Continued)

No.	No. of traps	Material	Amount used in each trap	Duration of expt.	No. of flies captured
10a	1	Phenol	57 gm.		
		Distilled water	50 c.c.	68 hrs.	0
b	1	Distilled water (control)	50 c.c.	68 hrs.	0
c	1	Ammonium carbonate	57 gm.		
		Distilled water	50 c.c.	68 hrs.	0
11a	2	Hydrogen sulphide solution	90 c.c.[1]	120 hrs.	1 male
b	1	Distilled water (control)	90 c.c.[1]	120 hrs.	0
12a	2	Ammonium sulphide solution	30 c.c.[2]	147 hrs.	1 male 1 female
b	1	Distilled water (control)	30 c.c.[2]	147 hrs.	0
13a	1	Carbon dioxide	64 gm. calcium carbonate 250 c.c. N/5 HCl	27 hrs.	0
b	1	Distilled water (control)	64 gm. calcium carbonate 250 c.c. distilled water	27 hrs.	0
14	1	Carbon dioxide	71 gm. calcium carbonate 200 c.c. normal HCl	25 hrs.	0
15	1	Ammonium hydroxide (14%)	500 c.c.	25 hrs.	3 females

[1] In three installments of 30 c.c. each.
[2] In three installments of 10 c.c. each.

a distance of fifteen feet from the traps. No record of the sexes of flies captured was obtained. Ethyl alcohol (see controls) traps caught an insignificant number of flies.

Butyric, acetic, formic, and valerianic acids and phenol gave only negative results. Ammonium carbonate exposed at the same time in certain experiments almost always attracted female flies.

Of the inorganic compounds, hydrogen sulphide solution, ammonium sulphide solution and carbon dioxide gave negative results. Ammonium hydroxide was positively attractive in one experiment in which three female house-flies were captured in a single trap during twenty-five hours exposure. No other ammonium hydroxide trap experiments were attempted.

Oviposition Experiments With Acidulated Horse Manure.

The purpose of this series of experiments was to show whether fresh horse manure which did not volatilize ammonia would still be a suitable nidus for the deposition of house-flies' eggs and whether such manure when again volatilizing ammonia would attract the female fly. If the manure were treated with hydrochloric acid, all the uncombined ammonia would unite with the acid to form ammonium chloride, a non-volatile salt at the ordinary temperature. Then if the ammonium carbonate were placed in the manure, it would again volatilize ammonia.

The preparation of the acidulated manure was as follows: a quantity of fresh horse manure was covered with a dilute solution of hydrochloric acid and the two were thoroughly mixed. After several hours, the acid liquor was poured off and the manure was drained. Before and after each experiment, the manure was tested with litmus paper to be sure that there was a surplus of acid to combine with any ammonia which might be produced during the experiment.

Porcelain evaporating dishes, 120 mm. in diameter and 35 mm. in depth inside were used as containers. Each was filled level full with the acidulated manure. Pieces of ammonium carbonate were imbedded in the manure and covered. Fifty-seven grams was the amount generally used. Ammonium hydroxide was used in two experiments, but was not entirely successful because the ammonia escaped rapidly and the addition of a liquid made the manure too wet. The controls contained only acidulated manure.

The lots of manure (each evaporating dish with its contents constituting a lot) were placed on the window sills of the laboratory in groups of two, 2 feet apart. The control lots were placed 2, 25, 30 or 50 feet from the lots containing ammonium compounds. In one experiment the ammonium carbonate was not placed in the manure, but in a glass dish and one lot of acidulated manure without ammonium carbonate was set on each side of it twelve inches distant.

In taking account of results every egg cluster which contained two or more eggs was considered an egg mass. The large majority contained many more than two eggs. Occasional scattered single eggs were ignored.

The six experiments are detailed in Table C.

TABLE C.

No.	Treatment of each lot	No. of lots	Distance from ammoniated lots	Duration of expt.	No. egg masses	Remarks
1a	57. gm. ammonium carbonate..	2	....	3 hrs.	27	
b	25 c.c. ammonium hydroxide (28%)	2	....	3 hrs.	0	Very wet. 2 hrs. later 8 egg masses were found on exposed dry portion.
c	Control (HCl manure)	2	2 ft.	3 hrs.	6	
2a	10 c.c. ammonium hydroxide (28%)	2	....	3 hrs.	6	Surface wet.
b	57 gm. ammonium carbonate..	2	....	3 hrs.	20	
c	Control (HCl manure)	2	25 ft.	3 hrs.	0	3 egg masses 41 hrs. later.
3a	71 gm. ammonium carbonate...	2	....	21 hrs.	29	
b	Control (HCl manure)	2	2 ft.	21 hrs.	6	
c	Control (HCl manure)	2	50 ft.	21 hrs.	0	
4a	57 gm. ammonium carbonate...	2	....	21 hrs.	33	
b	Control (HCl manure)	2	2 ft.	21 hrs.	6	
c	Control (HCl manure)	2	50 ft.	21 hrs.	3	
5a	57 gm. ammonium carbonate...	2	....	27 hrs.	55	
b	Control (HCl manure)	2	2 ft.	27 hrs.	7	
c	Control (HCl manure)	2	50 ft.	27 hrs.	2	
6a	Control (HCl manure)	2	1 ft.	24 hrs.	12	57 gm. ammonium carbonate + 50 c.c. distilled water in glass dish placed between controls (a).
b	Control (HCl manure)	2	30 ft.	24 hrs.	0	

Total egg masses in 10 lots of HCl manure evolving ammonia from ammonium carbonate 164
Average per lot 16.4

Total egg masses in 4 lots of HCl manure evolving ammonia from ammonium hydroxide 14
Average per lot 3.5

Total egg masses in 10 lots of HCl manure 1 to 2 ft. from ammoniated lots..... 37
Average per lot 3.7

Total egg masses in 10 lots of HCl manure, 25, 30 and 50 ft. from ammoniated lots. 8
Average per lot 0.8

in which smaller glass receptacles were substituted. A piece of sterilized absorbent cotton with a surface as large as the dish was placed in each. When ammonium carbonate was used it was always covered by the cotton and the water and other fluids were poured upon the surface of the cotton. Fifty centimeters of water were sufficient to keep it moist, but not excessively wet.

For the filter paper experiments, the paper was torn into bits, moistened with water and placed over the ammonium carbonate. In one series both the ammoniated and control lots contained paper stained with aqueous Bismark brown.

Most of the experimenting was done on the window sills of the laboratory, but two experiments were conducted at a livery stable. Usually two dishes were placed two feet apart on each window sill and from three to five feet separated one window sill from its neighbors. At the livery stable the dishes were located in a single row, each dish separated from the others nearest to it by two feet.

The result from eleven experiments are contained in Table E.

Eighteen egg masses were found in the ammonium carbonate-butyric acid dishes, an average of 2.57 for each; 3 egg masses were found in the ammonium carbonate—valerianic acid dishes, average 0.42 per dish; only one egg mass was found in the dishes which contained ammonium carbonate alone, average 0.09 per dish. The eggs were in every case deposited upon the cotton.

Butyric and valerianic acids as in the trap experiments were unattractive when used alone. Skatol, indol and phenol when added to dishes containing ammonium carbonate did not cause flies to oviposit on the cotton. Ammonium sulphide solution also gave negative results.

Butyric acid and to a lesser extent valerianic acid considerably augmented the oviposition response of the female fly when added to ammonium carbonate and cotton. Ammonium carbonate and cotton, without the aid of these acids, brought forth an almost negative response.

When ammonium carbonate was placed in dishes and covered with bits of moist filter paper, unstained or stained brown with aqueous Bismark brown, house-flies did not oviposit upon the filter paper or in the dishes.

TABLE E.

Material	No. of experimental dishes	Duration of experiments	No. of egg masses found
10 c.c. ammonium sulphide solution + 10 c.c. water + cotton	2	44 hours	0
57 gm. ammonium carbonate + 5 c.c. 0.3% absolute ethyl alcoholic solution of skatol + 50 c.c. water + cotton	1	46 hours	0
57 gm. ammonium carbonate + 5 c.c. 0.3% absolute ethyl alcoholic solution of indol + 50 c.c. water + cotton	1	46 hours	0
57 gm. ammonium carbonate + 5 c.c. absolute ethyl alcohol + 50 c.c. water + cotton	1	46 hours	0
57 gm. ammonium carbonate + 5 gm. phenol + 50 c.c. water + cotton	1	68 hours	0
57 gm. ammonium carbonate + 2-5 c.c. valerianic acid + 50 c.c. water + cotton	7	3-72 hours	3
57 gm. ammonium carbonate + 2-5 c.c. butyric acid + 50 c.c. water + cotton	7	3-72 hours	18
57 gm. ammonium carbonate + 20-50 c.c. water + cotton	11	3-72 hours	1
2-5 c.c. valerianic acid + 50 c.c. water + cotton	7	3-72 hours	0
2-5 c.c. butyric acid + 50 c.c. water + cotton	7	3-72 hours	0
20-50 c.c. water + cotton	4	3-72 hours	0
71 gm. ammonium carbonate + moist filter paper stained with Bismark brown and unstained	2	72 hours	0
Moist filter paper stained with Bismark brown and unstained	2	72 hours	0

Discussion.

A number of possible explanations of the small amount of oviposition in the distantly removed lots of acidulated manure are suggested by these experiments. (a) One or several chemical substances which were not tested may have been present in sufficient quantities to call forth a feeble oviposition response. (b) Gravid females, coaxed into the vicinity by the odor of ammonia may have come by chance to the acidulated control lots, when sight and the tactile sense would have helped them recognize these as suitable places for oviposition. (c) Gravid females may sometimes oviposit upon substances which do not emit an attractive odor, guided solely by sight or the tactile sense or both.

Of these three propositions, the second seems most in accord with the facts. The majority of the flies oviposited exactly at the source of ammonia if a suitable nidus was present, but not a few went a short distance away to lay their eggs. It is entirely possible that a small number would wander even farther and would eventually place their eggs on favorable substances some distance from the spot where the odor stimulus was first obtained.

The acidulated manure, timothy chaff, pine sawdust, cotton and filter paper to which ammonium carbonate and water only were added showed a decreasing number of egg masses in the order named. This decrease is correlated with a reduction in the food value (to the house-fly larvæ) of these substances. Eggs laid on timothy chaff hatched readily and the adult flies which emerged were normal. The larvæ which hatched in pine sawdust died long before the pupal stage was reached.

It appears from the above facts that the house-fly has some power of discrimination between substances containing high and low food values (for its larvæ) when attracted to them by the odor of ammonia. This power of selection is not infallible. It cannot be said at the present time whether this sense of discrimination is brought about by the olfactory, visual, gustatory or tactile senses or whether it is due to a "contact-odor" perception.

Moist ammoniated cotton was practically unsought for oviposition but the addition of butyric acid caused a large increase in the number of egg masses deposited. Valerianic acid showed a similar action, although the number of egg masses was smaller than in the

butyric acid series. Reactions between ammonium carbonate, butyric and valerianic acids resulted in the formation of small quantities (in these experiments) of ammonium butyrate and ammonium valerianate, both volatile salts. It can hardly be said that these compounds would raise the food value of cotton as larvæ were not able to live upon it when so treated. They may give to the cotton, however, an odor resembling horse manure since both butyric and valerianic acids are found in that substance. In this way flies might be tempted to oviposit on a substance which would not ordinarily attract them even though it evolved ammonia. Barrows (loc. cit.) observed in *Drosophila ampelophila* Loew, an increase in the attraction to ethyl alcohol when small quantities of butyric or valerianic acids were added.

The following conclusions are drawn from these experiments: (1) that house-flies are attracted to fermenting organic substances largely by the odor of ammonia, a product of this fermentation; (2) that ammonia attracts a preponderance of females; (3) that flies can be induced to oviposit upon certain substances near which ammonia is volatilized; (4) that flies lay their eggs by preference in organic substances which are capable of furnishing food for their larvæ and that they have some power which enables them to detect such substances; (5) that butyric and valerianic acids augment the oviposition response of the house-fly to ammoniated cotton.

The studies emphasize again the necessity for the proper disposal of all fermenting organic substances which volatilize ammonia and suggest new avenues of approach in the control of the house-fly.

parable Guthion treatment. The early parathion spray was considerably less effective than would be expected based on previous results (Smith 1952).

Parathion was most effective ovicidally and its ovicidal effectiveness was essentially equal to its total effectiveness except in the case of the first spray which for unexplained reasons gave lower total control than expected. Guthion also gave ovicidal control roughly equal to total control. In the case of Thiodan, total control was in all cases higher than ovicidal control. The 37% ovicidal effectiveness of the early Thiodan spray likely includes some eggs killed by residual ovicidal action. Effectiveness of organophosphates by this means has previously been cited (Smith 1954). The ovicidal action of Thiodan differed from that of the other materials as evidenced by embryos which punctured the chorion before death occurred. With all three materials, mature embryos were present in eggs which failed to hatch. The ovicidal effectiveness of Thiodan, a chlorinated hydrocarbon, is of special interest. The embryos appeared similar to those killed by organophosphates following inhibition of cholinesterase (Smith & Wagenknecht 1956) although the chlorinated hydrocarbons presumably act by a different mode of action.

Similar action by both organophosphates and chlorinated hydrocarbons against eggs of the pink bollworm has been reported by Brazzel & Gaines (1959).

The larvae varied greatly in size with extremes in head capsule measurement from 0.63 mm. to 3.80 mm. The number of instars and range in size of each has not been conclusively established although King & Morris (1956) report 5 to 7 with 6 the most likely number. The largest larvae were without doubt in the last instar and the smallest in the second or third instar. Only Thiodan in the late and combined treatment eliminated the smallest larvae which presumably hatched in early September approximately 4 weeks after the last spray. No mature larvae were represented in the survivors of the first Thiodan spray. Larvae of the current season hatched over the 6-week period from mid-July to early September and it is unlikely that many if any of these reached maturity by mid-October. The mature larvae are more likely the carry-over from the previous season, having a 2-year life cycle.

With each material the larvae surviving late treatment were larger than those from early treatment but these differences were not striking. The survival of some late larvae in all treatments except late Thiodan suggests the desirability of applying the last spray later in the season.

The fullest interpretation of these data requires additional information on the rate of larval development.

The foregoing data establish the striking effectiveness of Thiodan for control of the peach tree borer under New York conditions. Considering the severe infestation involved in these tests, satisfactory commercial control would be expected from a single spray allowing wide latitude in timing. Both parathion and Guthion are sufficiently effective for continued use in the recommended 2-spray program. These results indicate several areas deserving further study. Thiodan has been shown to exert some ovicidal effectiveness which likely involves a mode of action dissimilar to that of the organophosphates. It is also effective against established larvae suggesting its possible use in postharvest treatments. Interpretation of results of these treatments is limited by insufficient knowledge of the biology of the species, specifically rate of larval development.

REFERENCES CITED

Brazzel, J. R., and J. C. Gaines. 1959. The toxicity of several insecticides to eggs and larvae of the pink bollworm. Jour. Econ. Ent. 52(2): 301–3.

King, D. R., and H. F. Morris. 1956. Biologies of the peach tree borer and lesser peach tree borer in East Texas. Jour. Econ. Ent. 49(3): 397–8.

Peterson, Alvah. 1948. Larvae of Insects, part 1. Lepidoptera and Plant Infesting Hymenoptera. Edwards Brothers, Inc. Ann Arbor, Michigan.

Smith, E. H. 1951. Control of the peach tree borer and lesser peach tree borer in New York. Jour. Econ. Ent. 44(5): 685–90.

Smith, E. H. 1952. Control of the peach tree borer and lesser peach tree borer. Jour. Econ. Ent. 45(4): 611–5.

Smith, E. H. 1954. The ovicidal action of parathion in control of the peach tree borer. Jour. Econ. Ent. 47(5): 912–7.

Smith, E. H., and A. C. Wagenknecht. 1956. The occurrence of cholinesterase in eggs of the peach tree borer and large milkweed bug and its relationship to ovicidal action of parathion. Jour. Econ. Ent. 49(6): 777–83.

Chemical Attractants for the Adult House Fly[1]

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ABSTRACT

The development of chemical attractants as baits for the house fly (*Musca domestica* L.) is is described. A large number of compounds was first tested in an olfactometer. The materials which proved most attractive were tested in baited traps in a closed room. The best of these materials were then tested in the field in dry, open country, and in a humid area with rich vegetation. No single compound was so active that its attractiveness could not be enhanced by admixture. The most attractive material consisted of a combination, in aqueous solution, of malt extract 5%, ethyl alcohol 0.5%, skatole 0.02% and acetal 1%. For field use, 380 cc. of this attractant solution was made into a paste with 240 gm. of fine-ground peat and 40 gm. of alfalfa meal.

The development of insecticide resistance in house flies (*Musca domestica* L.) has focused interest on the possible use of attractants which would operate in the vapor phase and bring the flies into treated baits or traps. Apart from the question of the attractiveness of sugar (Dethier 1955, Acree *et al.* 1959), little has been published recently

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on the use of attractant vapors. The present paper summarizes studies on attractants performed some years ago, but of sufficient topical importance to be published at this time. The studies were based on experiments with an olfactometer under laboratory conditions, experiments with baited traps in a small room, and experiments with baited traps in open country.

OLFACTOMETER EXPERIMENTS.—The type of olfactometer used was a modification of the apparatus described by Wieting & Hoskins (1939). Essentially it consisted of a 1-foot cube, black, glass-lined chamber into which was fitted a wire cage containing some 400 flies. Two streams of air issued from an illuminated and heated warm-air chamber into the test chamber from a pair of adjacent ports, 1½ inches in diameter, midway up one side. A peephole in the side opposite allowed observation of the flies clustered at the ports. The streams of air were maintained at the rate of 3 to 4 litres per minute by a blower pump; air was drawn off from the floor of the chamber by aspiration at a slightly higher rate. The air delivered by pump was washed successively in normal sulphuric acid, normal sodium hydroxide, and distilled water. It was then divided into two streams, one passing through a 125-cc. gas-washing bottle containing an aqueous solution of the volatile compound being tested, and the other passing unchanged as the control. A three-way stopcock allowed the two streams to be interchanged.

During the major part of the experiments the environmental temperature was maintained at 29° C. and that of the air-stream at 37° C. When temperatures were 24° and 32° C., respectively, the results were unsatisfactory, since almost uniformly low attractiveness ratings were recorded.

The adult flies used were 1 to 3 days old, being a mixture of both sexes. They were put in the olfactometer cage, fed on fresh milk overnight and conditioned to the experiment room for 2 hours before use. The best results were obtained in the afternoon, probably because the flies became hungry at that time. Between experiments the cage of flies was put before an electric fan, a treatment which insured that they remained sensitive to odors. To counteract their pronounced response to moisture which would mask the differential between the two air-streams, the flies were kept well-supplied with water before use.

Counts were made of the flies at either port (the olfactory or the control) at 10-second intervals, 10 such counts generally providing sufficient data. After each run the flies were removed, the apparatus flushed out with air, and the experiment run again with the olfactory substance coming through the other port. The sum of the counts at the olfactory port, calculated as the percentage of the total counts at both ports, gave the olfactometer rating. In practice this was taken as the average of the ratings obtained from four runs, two on either side. Figures greater than 50 thus indicate that the material is attractive, and figures under 50 indicate that it is repellent.

The selection of the concentration of the compound in the aqueous solution was a matter of importance. A guiding consideration was offered by its volatility, and the strength of its odor to man. Compounds that were unattractive in moderate concentrations often proved to be very attractive in minute concentrations, and similarly other compounds that evoked no response in great dilution turned out to be attractive in higher concentration. In practice two or more concentrations of a substance were tested in order to "bracket" this effect.

Table 1.—Olfactometer, trap and field ratings of a group of substances attractant or repellent for house flies.[a]

SUBSTANCE	OLFACTOMETER RATING	TRAP RATING	FIELD RATING
Ethyl Alcohol	80 (0.2)[b]	166 (1)	87 (0.5)
Malt extract	85 (25)	100 (10)	100 (10)
Maltose	76 (10)	97 (10)	
Putrescine	60 (0.1)	96 (0.1)	
Skatole	80 (0.05)	80 (0.05)	51 (0.05)
Molasses	78 (10)	61 (10)	
Bromoform	64 (0.001)	52 (0.1)	15 (0.1)
Dimethyl-naphthylamine	77 (0.01 EtOH)	37 (0.1)	18 (0.1)
Dimethyl-aniline	66 (0.05)	36 (0.1)	11 (0.1)
Indole	61 (0.005)	33 (0.1)	14 (0.5)
Lactic acid	59 (10)	33 (5)	
Diethyl ether	71 (0.1)	31 (1)	25 (0.5)
Acetic acid	60 (0.4)	27 (1)	
Amyl acetate	59 (0.001)	24 (0.1)	14 (0.1)
Fresh milk	44	24	
Mesityl oxide	60 (0.001)	24 (0.1)	6 (0.1)
Quinaldine	68 (0.001)	23 (0.05)	13 (0.1)
Benzyl alcohol	66 (0.1)	23 (1)	17 (1)
Chloroform	71 (0.01)	20 (0.1)	
Ethyl mercaptan	54 (0.001)	20 (0.1)	6 (0.1)
Pyrrole	61 (0.1)	18 (0.1)	7 (0.1)

[a] Olfactometer ratings cannot be compared directly with trap and field ratings.

[b] Figures in parentheses indicate per cent concentration at which substances tested gave ratings shown.

Tests were run on various concentrations of approximately 75 compounds. These substances included alcohols, aldehydes and ketones, acids and phenols, esters, halogenated compounds, ethers and mercaptans, sugars, amines, nitrogenous heterocyclics, and impure substances such as malt extract and molasses. Results with the more active compounds are summarized in table 1.

An analysis of the results shows that the highest proportion of attractants is found in the following classes: sugars; amines,—aromatic, heterocyclic and aliphatic; halogenated compounds, ethers and mercaptans; aldehydes and ketones; and the alcohols. Acids, and more especially the esters, are characterized by surprisingly low attractiveness ratings in the olfactometer. The highest ratings of all were recorded for natural products of mixed nature, especially sugary ones undergoing fermentative change. Indeed, attractants as a whole may be grouped into either the products of putrefaction (principally amines) or of fermentation (aldehydes, ketones and alcohols), or of the basic carbohydrates (mono- or disaccharides).

Certain observations may be made from a detailed examination of the results. Among the alcohols, only the two lowest in the aliphatic series were attractive, and remained so even in moderately high concentrations. This is opposite to the finding of Speyer (1920) that alcohols, as well as aliphatic acids and aldehydes, were attractive only when the molecular weight exceeded 30. A low rating for amyl alcohol stands in contrast to the findings of Richardson (1917) that it was very attractive in baits. Of

the aromatic alcohols investigated, only benzyl alcohol was materially attractive.

Five out of the seven aromatic aldehydes and ketones tested were significantly attractive, the best being acetophenone and methylacetophenone; the attractiveness appeared only in very dilute solutions. The results for formaldehyde are contrary to the findings of its attractiveness by Laake *et al.* (1931) for the house fly in the field, and McIndoo (1935) for blow flies.

Acids and phenols as a group were low in attractiveness, and generally high concentrations were required for positive results. Both acetic acid and lactic acid proved to be attractive in these experiments, as in those conducted by Richardson (1917); on the other hand succinic acid, previously reported as an attractant, was not found to be attractive in our studies.

The esters, to our surprise, were not attractive for the house fly. Moderate dilutions were unattractive in the olfactometer. Further dilution decreased the apparent repellency, but only in one case did it raise the olfactometer rating above 50. Moreover, the results with any given ester were often extremely erratic.

All the sugars studied were markedly attractive. Yeast fermentation of these sugars greatly increased their attractiveness. It was remarkable that addition of 0.15% formaldehyde, itself unattractive in the olfactometer, to these sugars greatly enhanced their olfactometer rating. The natural compounds containing sugars included the two substances giving the highest ratings, namely malt extract and molasses. It was surprising to find that fresh milk, urine, and rotten meat (inoculated with *Escherichia coli*) were quite unattractive, although both fermented milk and sour milk were decidedly attractive.

Among the halogenated compounds investigated, chloroform and bromoform were notably attractive in extreme dilutions, while moderate concentrations were significantly repellent. Both diethyl ether and ethyl mercaptan proved to be attractive. Three types of artificial musks (methylated dinitro- and trinitro-benzenes) were investigated and found to be inactive, giving ratings of 50, 50 and 51.

The amines were found to include a number of attractants of considerable efficacy. Among the heterocyclic compounds, the weak attractiveness exhibited by the simpler pyridines is enhanced in the more complex quinolines, and still more so in compounds with the pyrrole nucleus, reaching a high point in skatole (β-methylindole, C_9H_9N, a constituent of feces, beetroot, nectandra wood and coal tar). All of the nitrogenous heterocyclics studied were attractive in very low concentrations. Among the simple amines, the aromatics are considerably more attractive than the aliphatics. The latter showed a steady rise in olfactometer rating as the chemical series was ascended, from 57 in trimethylamine (0.001%) to 69 in tributylamine (0.001%), and as the attractiveness of the low concentrations rose that of the moderate concentrations fell. It must be remarked that tributylamine proved unattractive in trap experiments, while trimethylamine was attractive. Although the naphthylamines were slightly repellent, the substituted anilines were even more attractive than the corresponding aliphatic series, the dimethyl-substituted tertiary amine being the most active.

While the ratings obtained for the most attractive material are reported quantitatively in table 1, the substances found to be less attractive, inactive or repellent, are listed herewith:

Substances Slightly Attractive at the Concentrations Tested (olfactometer rating >55%).—Ethyl alcohol, benzaldehyde, acetophenone, methyl-acetophenone, anisaldehyde, piperitone, thymol, sucrose, lactose, yeast-fermented sucrose, yeast-fermented lactose, acid-fermented milk, methylamine, trimethylamine, ethylamine, diethylamine, tributylamine, ethyl carbamate, ethylmethyl carbamate, morpholine, methylaniline, ethylaniline, diethylaniline, α,α-bipyridyl, isoquinoline.

Substances Inactive at the Concentrations Tested (olfactometer rating 55% to 45%).—Geraniol, formaldehyde, safrole, succinic acid, fumaric acid, p-aminobenzoic acid, p-toluenesulphonic acid, eugenol, linalyl acetate, terpinyl acetate, triethanolamine, aminodiethylaniline, α-naphthylamine, pyridine, piperidine, rotten meat.

Substances Repellent at the Concentrations Tested (olfactometer rating <45%).—Butyl alcohol, amyl alcohol, rhodinol, furfuraldehyde, citronellal, butyric acid, ethyl butyrate, ethyl acetoacetate, ethyl benzoate, urine.

TRAPPING EXPERIMENTS IN A SMALL ROOM.—The 40 materials which proved to be the most attractive in the olfactometer were then compared by trapping experiments. These were conducted in a bare, concrete-walled room 10′ by 16′ by 9′ high, with a window at one end. The average temperature was 23° C. The concentration of attractant selected for trap experiments was for most tests arbitrarily set at 10 times the most attractive concentration in olfactometer tests. The flies employed were similar in age and condition as for olfactometer tests. The solutions to be tested were added to absorbent cotton, 50 cc. to a 4″-square pad which was placed on white enamel plates under screen traps of the cone type. It was customary to run six traps at a time, arranged either in a hexagon whose diameter was 6 feet, or in a pentagon with the sixth trap in the center.

In order to obtain a comparative rating for these compounds and to eliminate the variable of the number of flies in the room at any one time, 10% malt extract solution was arbitrarily selected as a standard and was exposed in each experiment. Where the traps were arranged in a pentagon, the malt standard was placed in the center and the test substances rotated at intervals of 15 to 30 minutes. When the hexagonal arrangement was used, position error was overcome by making a second run with opposite traps interchanged.

Each experiment lasted 2 hours, at the end of which period the flies in each trap were anaesthetized and counted. The counts for any one substance were recomputed so that the rating of malt extract became 100. Each substance was tested four times, and the average of four counts was taken as the trap rating.

The 14 most attractive materials are listed in table 1 in the order of their trap rating. For comparative purposes their olfactometer ratings are also listed, as well as the ratings obtained in field trials. The latter ratings are also calculated on the basis of setting the results obtained with 10% malt extract at 100. The concentration of the compound is indicated in parentheses.

Ethyl alcohol proved to be the best attractant in these experiments, being the only compound to give a trap rating higher than the 100 of malt extract. Its attractiveness

has already been established by Richardson (1917) and by Wieting & Hoskins (1939) for the house fly, and by McIndoo (1935) for blow flies. It was noted that alcohol compared more favorably against malt extract when the flies were fully fed, and less favorably when they were hungry.

Maltose was slightly less attractive than malt extract, a status probably held by most sugars, and by molasses. The next compound, pure putrescine, was available as its crystalline hydrochloride and dissolved in N/100 NaOH to free the base; as it happened, although alkaline to phenolphthalein, the solution was almost odorless to the human, although proving to be highly attractive to flies. Skatole gained a high trap rating, as suggested by the olfactometer results, although the flies' reaction to it was definitely erratic; indeed Richardson (1916) found it to be quite unattractive in his field experiments on house flies. Bromoform, the next compound, was found to be the very best attractant for *Musca* by Laake *et al.* (1931) in field experiments in Texas.

Dimethyl-naphthylamine and dimethyl-aniline are two new attractants discovered by these experiments, both being methyl-substituted tertiary amines. Indole, like skatole, was found to be unattractive by Richardson (1917), but was reported by Hobson (1938) to induce oviposition in the sheep blow fly. Both lactic and acetic acids had been found by Richardson (1917) to be attractive in laboratory experiments, but in the field acetic acid was unattractive to *Musca*, and lactic acid unattractive to *Lucilia*. The attractiveness of diethyl ether has not been reported by any previous workers. Amyl acetate is listed by Ripley & Hepburn (1929) as an attractant for the house fly.

Fresh milk was found to be only moderately attractive. Mesityl oxide, benzyl alcohol, quinaldine and acetophenone represent four new attractants brought to light by this work. Both chloroform and ethyl mercaptan have already been found to be very attractive in the field by Laake *et al.* (1931). Pyrrole, chemically related to indole and skatole, and trimethylamine, a tertiary amine present in dead fish, were found to be attractive. Methyl-acetophenone and morpholine are two more compounds whose attractiveness represents a new discovery.

Ripley & Hepburn (1929), after an extensive study of a large range of organic compounds as attractants for the fruit fly *Pterandrus*, concluded that no single compound was as attractive as the mixtures found in the better natural baits. The attractiveness of the mixture of volatile products of fermentation is well known. This was demonstrated in experiments with *Musca*. In peat-alfalfa pellets the attractiveness of fermenting malt extract was two to three times greater than that of nonfermenting malt. Malt in the early stages of fermentation exceeded all other compounds in attractiveness.

An experiment with six attractants was conducted in which the attractiveness of a compound alone was compared with its attractiveness when mixed with each of five other compounds. The substances used were representative of various classes of compounds, and consisted of: amyl acetate 0.1%, acetophenone 0.05%, dimethyl-aniline 0.1%, ethyl alcohol 1%, chloroform 0.1% and lactic acid 5%. The following conclusions were drawn from the results:

a. In general, the effect of a mixture of two substances upon attractiveness is additive.

b. In each case the attractiveness of the substance alone was roughly double its trap rating as previously established. Possibly the presence of mixtures containing the same substance sensitized the flies and pointed the way to the pure substance.

c. Additions to a strong attractant such as ethyl alcohol did not increase its attractiveness, but actually decreased it relative to the pure substance alone.

d. Chloroform was incompatible with the other compounds, almost halving their attractiveness. Likewise dimethyl-aniline and acetophenone were incompatible.

Some of the best attractants are characterized by a high volatility and would therefore exist for a short period in a bait. Experiments were made on several substances having the property of retarding volatilization, thus simulating the gradual release of attractants in fermentation. These retardants, used in 0.1% concentration, were tested for their effect on 0.2% ethyl alcohol exposed under traps. Tall oil acids and dibutyl phthalate proved suitable as retardants by raising the relative attractiveness on the second day. Castor oil acids and acetylated castor oil raised the attractiveness initially but not after the second day. Another retardant, astratone, showed these same qualities when tested in peat-alfalfa pellets.

FIELD EXPERIMENTS IN DRY COUNTRY.—In order to test further the results of olfactometer and baited-trap trials, a series of experiments was carried out in the field with traps baited, as in the laboratory trials, with various attractants. The trials were carried out in open prairie-like country. The only vegetation in the area was short grass and low herbage which at the time was dry and brown. The temperature on the days of the trials varied from 65° to 70° F. at noon and was about 40° at night. The days were bright and clear; wind velocity varied from 5 to 10 miles per hour and the relative humidity was about 25%.

The attractant solutions were added to absorbent cotton on white enamel plates and placed under conical fly traps as described for the laboratory trap experiments. The original plan was to place these baited traps in circular layouts at 50 and 100 yards from a central point at which the flies were liberated. After it was found that the greatest catches were obtained in the traps located downwind from the point of liberation, regardless of the type of bait they contained, all traps were positioned downwind.

Traps were set out on an arc 100 yards downwind from the central point and were placed in three rows, on a frontage of 75 yards, each row 5 yards beyond the preceding, with 16 traps in each row or a total of 48 traps to a trial. Eight attractants were compared in a trial, and each attractant was represented by six traps arranged in a random manner.

Any permanent change of wind direction during the trial was corrected for by moving the traps. The flies were liberated in the morning and the catch of flies in the traps was counted the next morning.

The 14 substances which gave the highest ratings in olfactometer and laboratory-trap trials were tested in this manner and rated against 10% malt extract taken as a standard of 100. Each substance was tested in five trials on different days. The results are given in table 1.

It will be noted that the rankings obtained by the

Table 2.—Degree of attractancy of five combination baits for *Musca* and *Drosophila*.*

Attractant and Per Cent of Substances Used	Musca		Drosophila	
	No. of Flies	Rating	No. of Flies	Rating
Malt, 5 Ethyl alcohol, 0.5 Skatole, 0.02	182	100	257	100
Malt, 5 Ethyl alcohol, 0.5 Skatole, 0.02 Acetaldehyde, 1 Acetal, 1	340	187	1,063	414
Malt, 5 Ethyl alcohol, 0.5 Skatole, 0.02 Acetaldehyde, 1 Diacetyl, 1	244	134	606	236
Malt, 5 Ethyl alcohol, 0.5 Saktole, 0.02 Acetal, 1	548	300	2,028	789
Malt, 5 Ethyl alcohol, 0.5 Skatole, 0.02 Diacetyl, 1	140	77	1,208	470

* Summary of 18 observations over a period of 3 days. Ratings calculated on the basis of malt-alcohol-skatole taken as 100.

three methods are essentially similar. It is also apparent that the field trap experiments show much greater difference in attractiveness than the other two methods. The volatility of substances in the open probably accounts for these differences. If reliance is placed mainly on the field trials, then malt extract and ethyl alcohol must be regarded as far superior to the other substances tested. On the basis of the laboratory trap results, skatole takes its place alongside these two powerful attractants. On the basis of olfactometer results alone, five or six of the substances will be included as almost equally attractive. From the three sets of data it may be concluded that malt extract, alcohol and skatole, in the order named, are the most attractive of the substances tested for these flies.

In the dry prairie-like region where the trials were carried out, no native house fly population was present, and the house flies which were attracted to the baits were those which had been liberated. At the same time certain wild flies were attracted to the baits. These were counted and gave some incidental data on the attractiveness of the substances tested. The native flies included representatives of *Phormia*, *Sarcophaga* and *Calliphora* spp. as well as some anthomyiids. The preference of all four groups appears to be very similar to that of *Musca*, with the exception of the Anthomyiidae, which show a predilection for skatole and to a lesser degree for indole. As these were primarily dung flies, this is to be expected.

Field Experiments In a Humid Region.—In connection with the development of an attractant for *Drosophila* flies (West 1961), several substances were tested which had not been previously tried with house flies. The substances which proved highly attractive to *Drosophila* were acetal, diacetyl, and acetaldehyde. A series of five baits was mixed in which these substances were added in various combinations to the malt-alcohol-skatole attractant as indicated in table 2. For field use the attractants were made into a paste with fine-ground peat and alfalfa meal in the following proportions:

attractant solution	380 cc.
fine-ground peat	240 gr.
alfalfa meal	40 gr.

Traps baited with these mixed baits were set out in groups of five, one trap with each bait, at 12 stations 30 to 120 yards in several directions from the point of release of 50,000 laboratory-reared house flies. The test area was a sandy plot interspersed with small ponds and swamps. The vegetation of grass, rushes and shrubs was luxuriant and there was much decaying vegetable material in the swamps and shallow ponds. During the test, day temperatures ranged from 60° to 75° F., the humidity was high, wind 2 to 12 miles per hour and the sky clear. Counts of the number of flies trapped by each bait were made some 18 times during a period of 3 days. The totals of these counts are shown in table 2. It is recognized that the "fly factor" of Barnhart & Chadwick (1953) may have influenced the absolute numbers of flies trapped.

It is apparent that the addition of 1% acetal significantly increases the attractiveness of the malt-alcohol-skatole mixture to the house fly. This combination thus becomes the most attractive material yet discovered for *Musca*, as indeed it is for *Drosophila* (West 1961).

References Cited

Acree, F. Jr., P. L. Davis, S. F. Spear, G. C. LaBrecque, and H. G. Wilson. 1959. Nature of the attractant in sucrose fed on by house flies. Jour. Econ. Ent. 52: 981–5.

Barnhart, G. S., and L. E. Chadwick, 1953. A "fly factor" in attractant studies. Science 117: 104–5.

Dethier, V. G. 1955. Mode of action of sugar-baited fly traps. Jour. Econ. Ent. 48: 235–9.

Hobson, R. P. 1938. Sheep blow fly investigations VII. Observations on the development of eggs and oviposition in the sheep blow fly, *Lucilia sericata* Meig. Ann. Appl. Biol. 25: 573–82.

Laake, E. W., D. C. Perman, F. C. Bishopp, and R. C. Roark. 1931. The chemotropic responses of the housefly, the green bottle flies, and the black blow fly. U. S. Dept. Agric. Tech. Bull. 270: 10 pp.

McIndoo, N. E. 1935. Olfactory responses of blow flies with and without antennae, in a wooden olfactometer. Jour. Agric. Res. 46: 607–25.

Richardson, C. H. 1916. The response of the housefly to ammonia and other substances. N. J. Agric. Exp. Sta. Bull. 292.

Richardson, C. H. 1917. The response of the housefly to certain foods and their fermentation products. Jour. Econ. Ent. 10: 102–109.

Ripley, L. B. and G. A. Hepburn, 1929. Studies on reactions of the Natal fruitfly to fermenting baits. Union South Africa, Dept. Agr., Ent. Mem. 8: 19–58.

Speyer, E. R. 1920. Notes on chemotropism in the housefly. Ann. Appl. Biol. 7: 124–140.

West, A. S. 1961. Chemical attractants for adult *Drosophila* species. Jour. Econ. Ent. 54(4): 677–81.

Wieting, J. O. G. and W. N. Hoskins. 1939. The olfactory responses of flies in a new type of insect olfactometer. II. Responses of the housefly to ammonia, carbon dioxide and ethyl alcohol. Jour. Econ. Ent. 32: 24–29.

The Influence of Various Levels of Ground Ear Corn and Alfalfa Hay in the Bovine Diet on the Development of the Face Fly[1]

J. A. MEYER[2], C. M. CHRISTENSEN, AND F. W. KNAPP[3]

Department of Entomology, University of Kentucky, Lexington 40506

ABSTRACT

Environ. Entomol. 7: 829–830 (1978)

Ground ear corn was fed to an Angus cow in increasing percentages to study the effect of fecal pH, percent fecal moisture, and percent fecal crude protein on larval mortality and pupal weight of the face fly, *Musca autumnalis* DeGeer. As the percent ground ear corn in the bovine diet increased, the percent mortality of face fly larvae developing in the feces tended to increase, with 100% mortality occurring in the feces after the bovine had consumed 5.448 kg of ground ear corn. Fecal pH fell from 6.92 to 5.58 and percent moisture and percent crude protein varied slightly as the percent ground ear corn in the diet increased.

The physical and chemical make-up of bovine feces has been shown to vary as high-energy feeds are substituted into the diet for alfalfa hay or roughage. These variations may possibly affect the development of face fly larvae. Bay et al. (1969) studied the influence of fecal moisture content on oviposition and subsequent development of face flies. They obtained maximum pupal weights when face flies developed in feces of higher moisture content such as a roughage diet supplemented with grain. Alfalfa hay diets gave moist but firm feces and poorer face fly development. A low-moisture feces resulting from a prairie hay diet gave the poorest face fly development.

A high-grain or high-energy bovine diet produces feces having a significantly lower pH than feces resulting from a bovine maintained on pasture or roughage. Tremere et al. (1967) monitored ruminal pH of heifers fed predominantly wheat. They noticed a characteristic drop of pH from 7.2 to 5.0 as the daily intake of wheat increased.

Alfalfa hay is regarded as a good source of crude protein for bovine diets. As high-energy feeds, such as ground ear corn, are substituted into the ration for alfalfa hay, the crude protein content of the diet and the feces could possibly decrease. It is possible that one or more of these factors could modify or affect the development of face fly larvae in bovine feces. Ruprah and Treece (1968) reported that face fly survival was not significantly affected by the diet source of the feces in which they were reared. They did not, however, consider the quantity of grain which the bovine consumed for the diets tested. Meyer et al. (1978) did not recover face fly pupae from field-exposed fecal samples originating from bovines fed a high energy finishing ration. Face fly pupae were recovered from grass and an equal mixture of grass and grain feces.

The objective of this study was to determine the effect of various quantities of ground ear corn and alfalfa hay in a bovine diet on face fly larval mortality and pupal weight.

Materials and Methods

Two Angus cows, weighing ca. 340 kg each, were utilized for this study. One received free-choice alfalfa hay (control) and the other increasing quantities of ground ear corn and free-choice alfalfa hay (treated). The treated animal initially received 0.908 kg of ground ear corn/day. The amount of ground ear corn fed to the treated animal was increased at the rate of 0.454 kg every 3 days. Twenty-four h after the 3rd day of feeding each specific amount of ground ear corn, a single fecal sample was taken. Sampling was discontinued when 100% mortality of face fly larvae developing in the treated cow's feces occurred on 2 consecutive samplings. Bioassays were conducted with recently hatched 1st-instar face fly larvae obtained from a laboratory colony. However, to insure a more homogenous face fly population for the bioassay, a separate parent colony was established, reared from the feces of a cow receiving a first-cutting alfalfa hay diet. Twenty-five larvae were placed in each of three 100-g subsamples of the treated and control feces. The container with the 100 g of feces was placed inside a 266-ml muslin-covered Dixie® cup containing sufficient sand for pupation. The samples were then placed in an incubator at 85% RH, 28°C, until pupation occurred, after which time the pupae were counted. The percent mortality of face fly larvae of each bioassay was recorded. Three subsamples of each fecal sample were weighed into previously dried and tared glass crucibles, then dried overnight at 105°C to determine the percent moisture.

The percent crude protein of each fecal subsample and the percent crude protein of the alfalfa hay and ground ear corn utilized in the study were determined by the Kjeldahl method of nitrogen determination (Anon. 1960). The pH of each fecal subsample was determined using a standard 2-bulb pH meter.

Results and Discussion

Table 1 summarizes the pH, percent moisture, and percent crude protein of the bovine feces resulting from consumption of the indicated amount of ground ear corn, and also the performance of the face fly larvae in terms of percent larval mortality and pupal weight. The drop in fecal pH seems to be directly related to increased percentages of ground ear corn in the bovine diet. Percent face fly larval mortality in the treated feces varied unpredictably in response to the lower amounts of grain consumed, but increased rapidly after the cow had consumed 4.540 kg of ground ear corn. Percent fecal moisture and percent fecal crude protein varied unpredictably as the amount of grain consumed by the animal increased.

Fecal pH seems to have a profound effect on face fly larval development, showing an indirect relationship with percent mortality. It is possible that face fly larvae may

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0046-0225/78/0608-2902$00.75/0

Table 1.—Effect of ground ear corn consumption on fecal pH, percent moisture, percent crude protein, and face fly larval mortality and pupal weight.

Grain kg/day	pH[a]		% moisture[a]		% crude protein[a]		% mortality[a]		Pupal weight[a] (mg)	
	C[b]	T[c]	C	T	C	T	C	T	C	T
0.908	7.11	6.92	89.34	87.44	10.18	11.06	40.00	22.68	19.1	23.4
1.362	7.09	6.81	89.76	88.35	9.80	11.35	40.00	21.36	19.3	23.8
1.816	7.27	6.79	86.38	85.74	11.96	14.28	45.36	40.00	23.0	25.5
2.270	7.36	6.72	86.47	86.22	12.42	13.13	9.36	4.00	18.8	29.1
2.724	6.92	6.42	86.91	85.91	12.15	13.19	21.36	66.68	22.5	28.2
3.178	7.02	6.37	88.05	87.84	12.15	14.42	12.00	42.68	22.6	30.2
3.632	7.03	6.33	87.72	85.46	12.04	15.24	24.00	20.00	21.2	28.7
4.086	7.41	6.19	86.23	87.06	10.71	12.94	14.68	14.68	17.8	25.7
4.540	7.28	6.02	84.03	86.83	11.65	15.56	10.68	68.00	21.1	20.9
4.994	7.25	5.91	88.97	88.91	11.98	12.91	22.68	72.00	21.3	20.4
5.448	7.19	5.79	87.81	86.03	10.76	11.82	33.36	100.00	18.9	—
5.902	7.11	5.58	86.23	85.97	12.66	11.15	36.00	100.00	19.4	—

[a] Avg of 3 subsamples.
[b] Control.
[c] Treated.

have a pH tolerance such as that exhibited by Morgan and Schmidt (1966) for the horn fly, *Haematobia irritans* L. They found no 1st-instar horn fly larvae to survive below a pH of 5.5. It is also possible that face fly larvae are sensitive to one or more of the organic acids known to accumulate in the bovine rumen after consumption of large quantities of high energy feeds (Tremere et al. 1967), rather than the hydrogen ion content.

Percent fecal moisture did not vary schematically as did pH, therefore it probably did not contribute to face fly larval mortality or pupal weight variation. Bay et al. (1969) found that weights of face fly pupae increased in response to the addition of grain to the bovine diet, but they attributed the difference to the increased moisture content of the grain feces as compared with the hay feces. The data in Table 1 suggest that fecal pH could also be a factor influencing pupal weight.

Kjeldahl analysis of the ration components showed the ground ear corn to have 16.73% crude protein and the alfalfa hay to have 19.08% crude protein. The difference between these 2 values was probably not great enough to significantly influence the crude protein content of the feces.

A differing complement of ruminal flora exists between a bovine maintained on alfalfa hay and a bovine maintained on grain or high energy feeds (Purser and Moir 1959, Warner 1965). Valiela (1969) stated that the main food of insects that occur in decaying organic matter is probably the microflora and not the substrate itself. This factor could possibly modify face fly larval development.

REFERENCES CITED

Anonymous. 1960. Association of Official Agricultural Chemists. Official methods of analysis. 9th ed.

Bay, D. E., C. W. Pitts, and G. Ward. 1969. Influence of moisture content of bovine feces on oviposition and development of the face fly. J. Econ. Entomol. 62: 41–4.

Meyer, J. A., C. M. Christensen, and F. W. Knapp. 1978. The influence of time of day, bovine manure type, and distance from a barn on the recovery of face fly and house fly pupae. Environ. Entomol. 7: 246–8.

Morgan, N. O., and C. D. Schmidt. 1966. The pH tolerance of horn fly larvae. J. Econ. Entomol. 59: 222–3.

Purser, D. B., and R. J. Moir. 1959. Ruminal flora studies in the sheep. IX. The effect of pH on the ciliate population of the rumen *in vivo*. Austral. J. Agric. Res. 10: 555.

Ruprah, N. W., and R. E. Treece. 1968. Further studies on the effect of bovine diet on face fly development. J. Econ. Entomol. 61: 1147–50.

Tremere, A. W., W. G. Merrill, and J. K. Loosli. 1967. Adaptation to high concentrate feeding as related to acidosis and digestive disturbances in dairy heifers. J. Dairy Sci. 51: 1065–72.

Valiela, I. 1969. An experimental study of the mortality factors of larval *Musca autumnalis* DeGeer. Ecol. Mongr. 39: 199–225.

Warner, A. C. I. 1965. Physiology of digestion in the ruminant. Butterworths. p. 346–59.

peach trees 1 and 6 times at monthly intervals and 12 times at semimonthly intervals beginning on May 4. Another formulation, containing 80 billion spores per gram, applied to peach trees in a similar program in 1960 was much more promising, especially when used in multiple applications. In the spring of 1961 the average number of live borers per tree was 0 in trees treated at semimonthly intervals, 2 in those treated at monthly intervals, 14.2 in those treated once, and 19.3 in those that remained untreated.

REFERENCES CITED

Hornstein, Irwin, W. N. Sullivan, Ching-hsi Tsao, and A. H. Yeomans. 1954. The persistence of lindane-chlorinated terphenyl residues on outdoors foliage. Jour. Econ. Ent. 47(2): 332–5.

Snapp, Oliver I. 1958. Trunk sprays for control of the peach tree borer. Jour. Econ. Ent. 51(4): 557–8.

House Fly Breeding in Oak Sawdust and Peanut Hulls Used as Bedding in Calf Pens[1]

DONALD MACCREARY and GEORGE F. W. HAENLEIN[2]

One of the authors (Haenlein) observed in 1960 that there seemed to be appreciably fewer larvae of the house fly (*Musca domestica* L.) in calf pens where oak sawdust was employed as a bedding material than in pens where other bedding materials were used. Accordingly, tests were begun in July 1961 to check further on this observation. Two concrete-floored pens were utilized. The pens were cleaned thoroughly and oak sawdust placed in one and peanut hulls in the other. Four calves of approximately the same size were placed in each of the pens. Additional clean bedding was applied as needed, usually each day.

A time interval of 24 days was allowed for the first two tests, and a 21-day interval for the third. At the end of each test, temperature and pH of the bedding in each pen were determined. Also samples of the bedding, approximately 1,000 cubic inches, were taken from two locations along the sides of each pen. These were placed in large lantern globes, provided with gauze covers and ¼" hardware cloth bottoms. The lantern globes were then placed over battery jars partially filled with water. Periodically, larvae and pupae were removed from the water and the emerged adults taken from the lantern globes.

After bedding samples were collected, the pens were thoroughly cleaned in preparation for the next test. To reduce position bias, the same type of litter was not used in either pen in successive tests.

The results of the tests are summarized in table 1. The first test showed 26 times as many flies in the peanut-hull bedding as in the sawdust, the second, eight times as many, and the third, 46 times as many. Temperatures at the bottom of the bedding were 10° F. higher where the peanut hulls were used. A trend toward higher acidity in the peanut-hull bedding was noticeable.

Close observation when the pens were cleaned revealed even more clearly than the samples the differences in fly populations found in the two types of bedding. The following notes made at the time each pen was cleaned indicate these differences.

End of Test 1, "August 4, very few larvae observed in the sawdust pen. One small area 3'×3' had a few dozen larvae. This was the only concentration noted. The peanut-hull pen had very high concentrations of pupae in several areas along the wall (estimated at several thousands). A great quantity of pupae seen in the peanut hulls and only larvae in the sawdust (possibly indicating slower development). The peanut-hull manure was heating up while the sawdust was merely warm."

End of Test 2, "August 28, saw no larvae or pupae in sawdust pen. Both larvae and pupae seen in different sections of the peanut-hull pen. Not so numerous as on August 4."

Table 1.—House fly population, temperature and pH of sawdust and peanut-hull bedding.

Test Number[a]	Sawdust			Peanut Hulls		
	Temperature (°F.)	pH	Flies 1,000 Cu. In.[b]	Temperature[c] (°F.)	pH	Flies 1,000 Cu. In.
1	—	—	124	—	—	3,294
2	92	7.2	46	92	6.8	365
3	82	7.6	19	92	7.5	915
Average	92	7.2–7.6	64	92.0	6.6–7.5	1,530.6

[a] Test 1, July 17—August 4; Test 2, August 4—28; Test 3, August 28—Sept. 18.
[b] Includes larvae, pupae, and adults.
[c] At bottom of bedding.

End of Test 3, "September 18, very few larvae seen in sawdust pen. The pen with peanut hulls had one large mass of pupae (several hundred) in one corner. Small concentrations of larvae seen in many different areas of the pen."

Thus, both the test samples and general observations indicated a much lower fly population in the sawdust substrate. Certain speculations can be made as to the choice and/or suitability of sawdust as a house fly rearing medium. It packs much more firmly, is far less moist, and does not heat up as do peanut hulls. Possibly eggs were deposited on the fresh manure in both pens to the same extent but the environment may be less suitable for larval development in the sawdust. Other factors such as varying amounts of tannin, ammonia, and oxygen may contribute to the differences in fly production. From these observations it appears that the use of sawdust as a bedding material would reduce, rather markedly, the amount of house fly breeding in areas on a dairy farm where bedding is allowed to accumulate for various periods of time. For practical, low-cost utilization, the sawdust must be readily available at no great distance from the farm. It fails to heat up in winter to the same extent that peanut hulls or straw bedding do. Thus, to some dairymen it would be less desirable in the winter months. However, in both dry-lot feeding and loose handling systems its use during the fly breeding season should be of considerable value in reducing the house fly population.

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[2] Research Professor, Entomology, and Research Associate, Animal and Poultry Sciences, respectively, Delaware Agricultural Experiment Station, Newark.

A Natural Sex Lure Extracted from Female Pink Bollworms[1]

MILTON T. OUYE and B. A. BUTT, *Entomology Research Division, Agric. Res. Serv., U.S.D.A.,*[2] *Brownsville, Texas*

During investigations conducted on the mating habits of the pink bollworm (*Pectinophora gossypiella* (Saunders)), in preparation for later sterilization studies, a characteristic mating behavior of the males was observed. Prior to mating, males exhibited a state of excitation (premating dance) including rapid wing vibrations, with intermittent upcurving of the abdomen while stationary or crawling. In observations of 100 individual pairs of moths, it was noted that many males would exhibit the premating dance simultaneously, which was inevitably followed by mating of one of the pairs (Ouye & Richmond, unpublished data). This same phenomenon was also exhibited by males in 10 groups of 3 pairs of moths. During this period, all females remained quiescent except the one female about to mate. On one

[1] Accepted for publication March 2, 1962.

[2] In cooperation with the Texas Agricultural Experiment Station.

Biopesticide Reregistration Action Document

SILVER NITRATE

Case Number: 4082

Active Ingredient Code: 72503

Date Issued:

SEP 25 2001

Table of Contents

I. Executive Summary

A. IDENTITY

The technical grade active ingredient (TGAI) is a colorless, crystalline salt that is prepared by dissolving elemental silver in dilute nitric acid. The end-use product *Chrysal AVB*, (EPA Registration Number 72992-R), contains 2.83% silver nitrate and is manufactured by an integrated process. The product chemistry data submitted by the registrant, Pokon & Chrysal B.V., satisfies the requirement for product identity.

B. USE/USAGE

Chrysal AVB is a non-food/feed use biochemical pesticide. The end-use product, *Chrysal AVB* is plant regulator used as a conditioner and preservative (dip application) for fresh cut flowers to inhibit the formation of ethylene gas generated by cut flowers. The end-use product will be used in indoor storage facilities.

C. RISK ASSESSMENT

No unreasonable adverse effects to humans or to the environment are anticipated from aggregate exposure to silver nitrate when *Chrysal AVB* is used according to label directions. This includes all anticipated exposures for which there is reliable information.

1. Human Health Risk Assessment

a. Toxicological Endpoints

Mammalian acute toxicology data requirements have been submitted and satisfy the data requirements to support the registration. Data submitted for *Chrysal AVB* indicate Toxicity Category III for acute oral and dermal toxicity (LD_{50} > 2000 mg/kg males and females combined). The results of the primary eye irritation study in rabbits indicated *Chrysal AVB* is non-irritating (Toxicity Category IV). The primary dermal irritation study in rabbits showed that *Chrysal AVB* is only slightly irritating, with resolution by 24 hours (Toxicity Category IV). The acute inhalation toxicity data requirements were waived at the request of the registrant based on: *Chrysal AVB*'s low toxicity demonstrated in the submitted toxicity data; there is only a very remote possibility that respirable particles will be generated during the use of this product as a dip; and the toxicity data on silver and its salts, has been throughly reviewed and excepted in a Reregistration Eligibility Document (RED) on Silver and Silver Compounds.

b. Exposure Assessment

There is no expected dietary exposure and human exposure is expected to be very low because the product is for use as a dip in the cut flower industry. Moreover the precautionary label language will adequately mitigate these risks for workers. However, the Agency notes in the RED for Silver and Silver Compounds issued in 1993 that when excessive amounts of silver are introduced into the body, tissues become impregnated with silver sulfites, which form a

complex in elastic fibers. Large amounts of this complex under the skin will give it bluish, grey-blue, or in extreme cases a black color. This condition is called argyria. Although it is not a toxic effect and considered a cosmetic effect, argyria is undesirable and usually permanent. The Agency established a Oral Reference Dose (RfD) for silver at 0.005 mg/kg/day (IRIS 09/01/92). The RfD was based on the Gual and Staud 2-9 year human i.v. 1935 study, with an oral LOEL of 0.014 mg/kg. day, and an uncertainty factor of 3 to account for minimal effects in a subpopulation which exhibited an increased propensity for development of argyria. A conversion factor was used to convert intra.venous doses to oral doses (each intra.venous dose of 1 g. is divided by 0.04, an assumed oral retention factor). No uncertainty factor for less-than-chronic to chronic duration was needed since the dose has been appointed over a lifetime. The RfD has been verified (07/18/91 by the Agency (IRIS 09/01/92). Also, the Agency's Office of Drinking Water set a Secondary Maximum Contaminant Level (SMCL) of 100 μg/L for silver in drinking water. According to the Office of Water, the presence of silver in the public water supplies of 100 U.S. cities was reported to average 2.68 μg/L (2.68 ppb). The Agency's Office of Water estimates that a concentration of silver in water of 100 μg/L or 0.1 mg/l will not produce darkening of the skin and other cosmetic effects associated with argyria. Since the use dilution by weight for silver in *Chrysal AVB* is approximately 150 μg/L, the Agency is proposing the use of protective equipment (gloves made of impermeable material sufficient to cover the hands, wrist and forearm) to mitigate the occurrence of this condition in persons using silver nitrate as a plant regulator on flowers.

c. Risk Assessment

The Biopesticides and Pollution Prevention Division (BPPD) has not identified any subchronic, chronic, immune, endocrine, or nondietary exposure issues as they may affect children and the general U.S. population. The acute oral toxicity and dermal toxicity risks to applicators are mitigated as long as the product is used according to label directions. No toxicological endpoints have been identified, and there is limited exposure to this product when used according to label instructions. The Agency has considered silver nitrate in light of the relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and has determined that there will be no unreasonable adverse effect from the use of silver nitrate when used as a plant regulator for fresh, cut flowers.

2. Ecological Assessment

a. Non-target Organisms

Ecological effects data for biochemicals 40 CFR 158.690(d) - - §154.6 thru §154-11, are conditionally required for indoor and greenhouse use patterns. Although no ecological effects toxicological endpoints were identified by the registrant and no studies were submitted for review, the Agency has investigated short term toxicity studies on various animal species with elemental silver and silver compounds identified in the RED for Silver and Silver Compounds issued in 1993. Given the indoor use pattern for *Chrysal AVB* and the explicit disposal instructions for spent product, these precautionary labeling statements are expected to adequately mitigate risks to fish and aquatic organisms. The Agency is not requiring data for other non-target organisms

(birds, mammals, and insects) based on the minimal environmental exposure to *Chrysal AVB*.

c. Environmental Fate

Environmental fate studies are not required for biochemical pesticides unless triggered by adverse effects to non-target organisms. Further, the use of *Chrysal AVB* in enclosed areas (greenhouses and indoor cut flower storage areas) minimizes the chances of exposure for non-target organisms.

d. Risk Assessment

Risk to non-target organisms is expected to be minimal due to the low probability of exposure to the environment. Moreover specific precautionary labeling for fish and aquatic organisms and product disposal instructins should prevent exposure to drinking water and groundwater supplies. As a result, BPPD believes that the use of *Chrysal AVB* according to label use directions should result in no significant adverse effects to wildlife and the environment.

D. DATA GAPS / LABELING RESTRICTIONS

There are no data gaps or labeling restrictions. Because *Chrysal AVB* 's Toxicity Category III for acute oral toxicity, acute dermal toxicity, and it's high fish toxicity, explicit precautionary labeling are required to mitigate risks associated with the proposed uses (see Labeling Rationale).

II. OVERVIEW

A. ACTIVE INGREDIENT OVERVIEW

Common Name: Silver Nitrate

Chemical Name: Silver Nitrate, $AgN0_3$

Trade and Other Names: *Chrysal AVB*

OPP Chemical Code: 72503

Basic Manufacturer:

Pokon & Chrysal B.V.
Gooimeer 7
1411 DD Naarden
The Netherlands

U.S. Agent: James Kaplin
Pokon & Chrysal
3063 NW 21st Street
Miami, Florida 33172

B. USE PROFILE

The following is information on the proposed use with an overview of use sites and application methods.

Type of pesticide: Biochemical Plant Regulator

Use Sites: Cut flowers in indoor storage facilities.

Target: Ethylene gas generated by cut flowers.

Formulation Types: Soluble Concentrate (liquid)

Methods and Rates of Application: Mix *Chrysal AVB* with water at the rate of 1 ml per quart of water in a non-metallic container.

Use Practice Limitations: Specific pesticide disposal statements to neutralize pesticide residuals in order to mitigate surface water contamination are contained on the product label.

Timing: Place flowers in prepared solution immediately after cutting for a minimum of 2 hours and a maximum of 72 hours. Lilies should be treated for a minimum of 4 hours and a maximum of 36 hours.

C. ESTIMATED USAGE

This is the first registered use for this product. Usage will depend on acceptance in the marketplace by commercial flower distributors.

D. DATA REQUIREMENTS

The data requirements for granting this registration under Section 3(c)(5) of FIFRA have been reviewed by BPPD. The mammalian toxicology, product chemistry, and ecological effects data requirements for *Chrysal AVB*, active ingredient silver nitrate, have been fulfilled. Product analysis data requirements are adequately satisfied.

E. REGULATORY HISTORY

Silver nitrate was first registered as a pesticide by the United States Department of Agriculture in1962. On October 31, 1962 a registration was granted to U.S. Movidyn Corporation for, *AG 1227 For Control of Micro-organisms* (EPA Reg. No. 4855-6), to control slime-forming bacteria and mold in paper mills/water systems. This registration, along with four other product registrations containing silver nitrate as an active ingredient, were canceled on July

1, 1987 as a result of an Agency initiated generic data call-in, for which the registrants declined to provide data to support the continued registration of their products.

A Reregistration Eligibility Document (RED) for Silver and Silver Compounds was issued by the Agency in 1993 that stated silver and silver compounds (e.g. silver nitrate) were eligible for reregistration. On June 3, 1997 the Agency granted a registration to Active-Carb Ltd. for *Active-Carb Ltd. Type: PKU 47/25*, (EPA Reg. No. 70639-3), active ingredient silver nitrate, for control of gram-positive and gram-negative pathogenic bacteria in potable water. On July 21, 1998 this registration was canceled by the Agency for non-payment of registration fees.

As a result of an inquiry by the registrant, Pokon & Chrysal *B.V.*, dated May 11, 1998, the Biochemical Classification Committee of BPPD on November 23, 1998 determined that the active ingredient silver nitrate in *Chrysal ABV* was a biochemical pesticide. (See F., below). The classification of silver nitrate as a biochemical pesticide allows for an abbreviated registration process. Biochemical pesticides generally have non-toxic modes of actions, are naturally occurring and are used at low application rates. They can be registered using a reduced data set as specified in 40 CFR 158.690.

On December 9, 1999 the Agency received an application from Pokon & Chrysal *B.V.* to register *Chrysal AVB* active ingredient silver nitrate. Although the active ingredient has been previously registered as a pesticide, BPPD is treating this registration action as a registration of a "new chemical"since there are no current registrations. A Notice of Receipt of the Application for a n active ingredient not currently registered as a pesticide was published in the Federal Register on September 11, 2000 **(FR Vol. 65, No. 176, Page 54850)** with a 30-day comment period. Two comments were received as a result of this publication and are discussed in section IV.(B.) (Regulatory Position).

F. CLASSIFICATION

On November 23, 1998, the Biochemical Classification Committee of BPPD determined that *Chrysal ABV* (active ingredient silver nitrate) is a biochemical because it is natural occurring and has a non-toxic, indirect mode of action (i.e., inhibition of the generation of ethylene gas in fresh cut flowers to avoid premature shrinking or dropping of buds and blooms.).

G. FOOD CLEARANCES/TOLERANCES

A numeric tolerance or exemption from the requirement of a tolerance is not needed because there are no food uses associated with the registration of *Chrysal ABV*.

III. SCIENCE ASSESSMENT

A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for *Chrysal ABV* are satisfied.

1. Product Identity:

The active ingredient of *Chrysal ABV* consists of a 2.83% silver nitrate solution and is manufactured by an integrated system.

2. Mode of Action:

Chrysal ABV is used to prevent the formation of ethylene gas by cut flowers to avoid the premature shrinking or dropping of buds and blooms.

3. Physical and Chemical Properties Assessment

The physical and chemical characteristics of the end-use product *Chrysal ABV* were submitted to support the registration. They are summarized in Table 1 - - PRODUCT CHEMISTRY DATA.

Table 1 - - Summary of Product Chemistry Data - End Use Product.

Guideline No.	Study	Results	MRID No.
151B-10	Product Identity	EP contains 2.83% silver nitrate CAS No. 7761-88-8; 1.80%Ag^+	449918-01 449918-02
151B-11	Manufacturing Process		449918-01 449918-02
151B-12	Discussion of formation of unintentional ingredients	*Chrysal ABV* is produced by dissolving and mixing the active and inert ingredients. No impurities are formed during the production process.	449918-01 449918-02
151B-13	Analysis of Samples	Preliminary 5 batch product analysis was conducted with ICP-technique (AES). Results of this study showed that the average sliver content was consistent with the nominal silver content on the confidential statement of formula.	449918-01 449918-02
151B-15	Certification of Limits	The certified limits for silver nitrate agree with the product label. The proposed upper-lower limits of all of the ingredients are within guidelines recommended in OPPTS 830.1750.	449918-01 449918-02
151B-16	Analytical Method	The Official Methods of Analysis of the Association of Official Analytical Chemists (fifth edition, 1990) were submitted for the analytical method for enforcement. Ag^+ is determined by atomic adsorption spectrophotometry.	449918-01 449918-02
151B-17(a)	Color	Transparent	449918-01 449918-02
151B-17(b)	Physical State	Liquid	449918-01 449918-02
151B-17(c)	Odor	None	449918-01 449918-02
151B-17(d)	Melting Point	Not applicable; product is not a solid.	449918-01 449918-02
151B-17(e)	Boiling Point	100^0 C	449918-01 449918-02

151B-17(f)	Density	1.247 g/mL	449918-01 449918-02
151B-17(g)	Solubility	Soluble in water.	449918-01 449918-02
151B-17(h)	Vapor Pressure	Not required for end-use products.	
151B-17(i)	pH	5.7	449918-01 449918-02
151B-17(j)	Stability	Stable in a cool dark, frost-free place in the original tightly closed container.	449918-01 449918-02
151B-17(k)	Flammability	Not flammable.	449918-01 449918-02
151B-17(l)	Storage stability	At least 2 years in unopened packaging, if kept in a dark, cool and frost-free place.	449918-01 449918-02
151B-17(m)	Viscosity	Not reported.	449918-02
151B-17(n)	Miscibility	Not applicable, product is not an emulsifiable concentrate and is not likely to be diluted with petroleum solvents.	449918-02
151B-17(o)	Corrosion characteristics	Not corrosive to glass or plastic, but may be corrosive to metals; however, metal containers are prohibited in Directions for Use of this product.	449918-01 449918-02

B. HUMAN HEALTH ASSESSMENT

The acute toxicity information submitted in support of the application for registration of the end-use product *Chrysal ABV*, which has the active ingredient, silver nitrate, adequately satisfies the requirements set forth in 40 CFR 158.690(c) - - Biochemical pesticide for non-food use indoor uses. The overall toxicological risk from human exposure to silver nitrate in *Chrysal ABV* is considered negligible. See appendix A.

1. Toxicology Assessments for End-use Products

Adequate mammalian toxicology data conducted with the end-use product are available and support registration of the product, *Chrysal ABV*, containing the active ingredient silver nitrate. Refer to Table 2 - - Summary of Acute Toxicity Data Requirements: End-Use Product.

a. Acute Toxicity

The registrant submitted acceptable acute toxicity studies and requests for waivers for

certain requirements. Refer to Table 2. Summary of Toxicity Data Requirements: End-use Product.

Acute Oral Toxicity Study in Rats

Ten rats (5 of each sex) were given a single dose of 2,000 mg/kg of the test material by oral gavage. The test was carried out according to OECD guideline No. 401 (1987), "Acute Oral Toxicity." The test animals were observed for clinical signs and mortality. All rats survived throughout the study, appeared active, and healthy. All rats gained weight during the study. No gross abnormalities were observed. The LD_{50} was greater than 2,000 mg/kg; Toxicity Category III.

Acute Dermal Toxicity Study in Rats

Ten rats (5 of each sex) received a single dose of 2,000 mg/kg of the test material applied uniformly to the clipped back and flank (approximately 10% of the body surface) and the test site semi-occluded for 24 hours. The test was carried out according to OECD guideline No. 402 (1981), "Acute Dermal Toxicity." The test animals were observed for clinical signs and mortality frequently on the day of dosing and at least daily thereafter for 14 days. All rats survived throughout the study, appeared active, and healthy. All rats gained weight during the study. No gross abnormalities were observed. The LD_{50} was greater than 2000 mg/kg; Toxicity Category III.

Acute Inhalation Toxicity

The registrant, Pokon & Chrysal B.V., requested a wavier for conducting acute inhalation toxicity study with *Chrysal ABV* based on the following criteria: (1) There is virtually no possibility that respirable particles will be generated during use of this product; (2) Data reviewed by the Agency on *Chrysal ABV* demonstrates the product's low acute toxicity; (3) The toxicity of silver and silver compounds (i.e., silver nitrate) has been throughly investigated by the Agency and is well understood and documented in the RED for Silver and Silver Compounds issued in 1993, and in the open literature. The Agency agrees with the registrant and the waiver request is acceptable.

Primary Eye Irritation Study in Rabbits

Three rabbits (one female and two males) were given a dose of 0.1 ml of test substance. The test was carried out according to OECD guideline No. 405 (1987), "Acute Eye Irritation/Corrosion." The Draise method for scoring eye irritation and the Kay and Calandra method for interpreting the results of eye irritation tests were used. No corneal opacity, iritis, or conjunctival irritation were noted on any of the rabbits. The average ocular irritation index was 0. This classifies the test material as non-irritating; Toxicity Category IV.

Primary Dermal Irritation Study in Rabbits

Three rabbits were given a dose of 0.5 mL of test substance, and covered with semi-permeable dressing. The test was carried out according to OECD guideline No. 404 (1981), "Acute Dermal Irritation/Corrosion." The Draize method was used for scoring the results. Very slight erythema was noted on 2 out of 3 rabbits one hour after patch removal that was resolved by day 7. One rabbit had very slight erythema one hour after patch removal with resolution by 24 hours. Slight edema was noted on one rabbit one hour after patch removal that reduced to very slight by 24 hours and cleared by 48 hours. One rabbit had very slight edema one hour after patch removal with resolution by 24 hours. Primary irritation index was 0.8; Toxicity Category IV.

Hypersensitivity - Wavier Request for Further Testing

The registrant, Pokon & Chrysal B.V., requested a waiver for conducting a hypersensitivity study with *Chrysal ABV* based on the following criteria: (1) The results from a sensitization study with silver thiosulfate in guinea pigs (maximization test) indicate that the substance is a non-sensitizer; (2) The toxicity of silver and silver compounds has been thoroughly investigated by the Agency, is well understood and documented in open literature, and the RED for Silver and silver compounds which specifies that all requirements for acute toxicity testing on silver nitrate have been waived by the Agency, and (3) data submitted to the Agency on *Chrysal ABV* demonstrates the product's low toxicity. The Agency agrees with the registrant and the waiver request is acceptable. However, it should be clearly understood by the registrant (and future registrants) that **all incidents of hypersensitivity must be reported to the Agency** (40 CFR §158.690(c)).

Table 2 - - Summary of Acute Toxicity Data Requirements: End-Use Product

Guideline No.	Study	Results	MRID No.
152.10	Acute Oral Toxicity	LD_{50} > 2000 mg/kg (males, females combined). **Toxicity Category III.**	449918-03
152.11	Acute Dermal Toxicity	LD_{50} > 2000 mg/kg (males, females combined). **Toxicity Category III.**	449918-04
152.12	Acute Inhalation Toxicity	Waived	
152.13	Primary Eye Irritation	Not an irritant. **Toxicity Category IV**	449918-05

152-14	Primary Dermal Irritation	Very slight erythema on 2 out of 3 rabbits 1 hour after patch removal that persisted through 72 hours with resolution in 7 days; very slight erythema on 1/3 rabbits 1 hour after patch removal with resolution by 24 hours; slight edema on 1 rabbit 1 hour after patch removal that reduced to very slight by 24 hours and cleared by 48 hours; very slight edema on 1/3 rabbits 1 hour after patch removal with resolution in 24 hours. **Toxicity Category IV.**	449918-06
152-15	Dermal Sensitization	Waived	

b. Mutagenicity, Developmental Toxicity, and Immune Response

Studies to detect genotoxcity are only conditionally required for terrestrial, non-food use biochemical pesticides. 40 CFR 158.690.(c)(v) indicates that these studies are required if use is likely to result in significant human exposure, or if the active ingredient or its metabolites are structurally related to known mutagens or belong to a class of chemical compounds which contains known mutagens. The registrant requested a waiver of these studies based on the human exposure to the active ingredient (silver nitrate), when used in accordance with the label instructions in cut flower storage and processing areas, is anticipated to be very low due to the low application rates and protective gloves for workers. In addition, the active ingredient is not structurally related to a known mutagen, nor does it belong to a class of known mutagens. Since silver nitrate has been registered for approximately 30 years with significant human exposure and no reports of adverse effects. The Agency is granting a waiver for requiring these studies.

The Agency is not requiring the immune response study because of the low anticipated human exposure from labeled uses and no because there are no reports of adverse effects in humans after many years of significant human exposure. However, any incidents of hypersensitivity resulting from the labeled uses must be reported in accordance with 6(a)(2) of FIFRA. If such reports occur, this data (immune response studies) may be required at that time.

c. Subchronic Toxicity

The 90-Day Feeding Study was not required because of the non-food use proposed for *Chrysal ABV*, active ingredient silver nitrate. Additionally, the 90-Day Dermal and Inhalation Toxicity studies are not required because the proposed use pattern, a conditioner (dip application) for cut flowers, does not result in prolonged exposure at concentrations that are likely to be toxic.

d. Chronic Exposure and Oncogenicity Assessment

Chronic exposure studies are conditionally required to support non-food uses only if the potential for adverse effects are indicated based on (1) the subchronic effect levels established in Tier I subchronic oral, inhalation, or dermal studies, (2) the pesticide use pattern, or (3) the

frequency and level of repeated human exposure that is expected. Oncogenicity studies are required to support non-food uses only if the active ingredient or any of its metabolites, degradations products, or impurities produce, in Tier I studies, morphologic effects in any organ that potentially could lead to neoplastic changes. The Agency has determined that the triggers for chronic exposure and oncogenicity studies were not met.

e. Effects on the Endocrine System

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of the potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA, and to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening and additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

Based on the weight of evidence of available data, no endocrine system-related effects have been identified for silver nitrate, the active ingredient in *Chrysal ABV*.

2. Dose Response Assessment.

No toxicological endpoints are identified.

3. Dietary Exposure and Risk Characterization

Dietary exposure is unlikely to occur because of the non-food use of the end-use product, a conditioner(dip application) for fresh, cut flowers to inhibit the generation of ethylene gas that causes wilting and bud drop. In the absence of any toxicological endpoints, risk from consumption of silver nitrate residues is not expected for the general population including infants and children.

4. Occupational, Residential, School and Day Care Exposure and Risk Characterization

Significant human exposure to silver nitrate is not expected in residential, school and day care facilities from the use of silver nitrate as a cut flower treatment.

a.. Occupational Exposure

Based on its low toxicity and its use on cut flowers intended solely for aesthetic purpose, *Chrysal ABV* is not subject to the Worker Protection Standards (WPS), i.e., greenhouse workers.

Moreover the possibility for oral and dermal exposures are mitigated as long as the product is used according to label directions. The Agency notes in the RED for Silver that when excessive amounts of silver are absorbed, tissues become impregnated with silver sulfites, which form a complex in elastic fibers. Large amounts of this complex under the skin will give it bluish, grey-blue, or in extreme cases a black color. This condition is called argyria. Although it is not a toxic effect, argyria is undesirable and usually permanent. To this end, the Agency is requiring the use of protective equipment (gloves made of impermeable material sufficient to cover the hands, wrist and forearm) to mitigate the occurrence of this condition.

b. Residential, School and Day Care Exposure and Risk Characterization

No indoor residential, school, or day care uses are currently proposed for products containing silver nitrate. Human exposure should not occur in these areas.

5. Drinking Water Exposure

Exposure to silver nitrate is not expected. Product labeling regarding disposal of spent product directs the users to follow specific disposal practices designed to chelate silver nitrate from solution and offer it for waste recycling. Also, there is specific label restrictions prohibiting the disposal of wastes in a municipal sewage system.

6. Acute and Chronic Dietary Risks for Sensitive Sub-populations Particularly Infants and Children

There are no food uses associated with the proposed use of *Chrysal ABV*, active ingredient silver nitrate. Therefore, the acute dietary risks should be negligible based on lack of exposure.

7. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

Aggregate exposure would primarily occur to floral workers handling cut flowers through dermal and eye irritation routes. Risks associated with the dermal and eye irritation aggregate exposure of silver nitrate are measured via the acute toxicity studies submitted to support registration of *Chrysal ABV*. Results of the acute oral and dermal toxicity studies indicated low toxicity (Toxicity Category III) and primary eye irritation and primary dermal irritation (Toxicity IV). Based on these results, the anticipated risks from oral and dermal toxicity, as well as eye irritation are considered minimal. The inhalation toxicity (Category IV) was waived because of: low toxicity of silver nitrate; there is virtually no probability that respirable particles will be generated during the labeled uses of *Chrysal ABV*; and the toxicity of silver and silver compounds is well understood and documented by the Agency in the RED for Silver and Silver Compounds (1993). Therefore, the risks from aggregate exposure to silver nitrate via oral, dermal and eye exposure are a compilation of three low risk exposure scenarios and are considered negligible.

8. Cumulative Effects

The toxicity of silver and silver compounds is well understood and documented by the Agency in the RED for Silver (1993). Silver nitrate is not toxic. Therefore, there would be no

expected cumulative effects from common mechanisms of toxicity.

C. ENVIRONMENTAL RISKS

1. Ecological Effects Hazard Assessment

The end-use product, *Chrysal AVB*, is intended for use in non-food indoor areas. When used according to label directions, no direct exposure of birds, fish, aquatic organisms, and non-target species is expect to occur. Although no non-target organism toxicology studies were submitted by the registrant, the Agency has investigated short term toxicology studies on various animal species with silver nitrate identified in the RED for Silver and Silver Compounds issued in 1993. Silver and silver compounds, such as silver nitrate, are known to be highly toxic to fish and aquatic organisms. The RED specified that certain precautionary labeling is appropriate to mitigate risks for fish and aquatic organisms. Given the indoor and greenhouse uses for the end-use product, *Chrysal AVB*, precautionary product labeling regarding fish toxicity and disposal of spent product is expected to adequately mitigate risks to fish and aquatic organisms. Refer to IV. RISK MANAGEMENT DECISION, C. Labeling Rationale.

2. Environmental Fate and Groundwater Data

The RED for Silver and Silver Compounds determined that products containing silver and silver compounds are not to be applied in marine/estuarine environments or oil fields. Discharge of silver-containing effluents into lakes, streams, ponds, estuarinies, oceans or other waters are subject to National Pollutant Discharge Elimination Systems (NPDES) permit restrictions. In addition, waters treated with silver as a pesticide cannot be discharged into sewage systems without notifying the sewage plant authority. Again, given the indoor and greenhouse uses for the end-use product, *Chrysal AVB*, specific precautionary product labeling regarding disposal of spent product is expected to adequately mitigate environmental and groundwater risks. Refer to IV. RISK MANAGEMENT DECISION, C. Labeling Rationale.

3. Ecological Exposure and Risk Characterization

Minimal potential for exposure exists to non-target wildlife as a result of this proposed use of silver nitrate in the end-use product, *Chrysal ABV*.

D. EFFICACY DATA

No efficacy data was required at this time because no public health uses are involved.

IV. RISK MANAGEMENT DECISION

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will preform its intended function without unreasonable adverse effects on the environment and (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

To satisfy criteria "A" above, silver nitrate in the product *Chrysal ABV* is not expected to cause unreasonable adverse when used according to the label instructions. Criteria "B" is satisfied by current label and by data presented in this document. It is believed that this pesticidal active ingredient will not cause any unreasonable adverse effects, will extend the life and preserve cut flowers through the mitigation of ethylene gas as claimed in satisfying Criteria "C." Criteria "D" is satisfied by the data submitted and the low exposure to the product when used according to label directions.

Therefore, silver nitrate is eligible for registration. Registered uses are listed in Table 3 -- Use Sites For The Product, in Appendix A.

B. REGULATORY POSITION

The Agency received several comments from two commentors in response to the FR Notice of Receipt of a New Active Ingredient published September 11, 2000 **(FR Vol. 65, No. 176, p 54850).** These comments were directed to issues regarding the classification of silver nitrate as a biopesticide and toxicity to humans and the environment with respect to the release of silver nitrate residues into the ecosystem.

One commentor stated that silver nitrate is not a naturally occurring material, and, therefore, is not a "biological pesticide". Also this commentor mentioned that silver nitrate does not appear to fall within the three major categories of biopesticides recognized by the Agency.

Both respondents to the FR Notice presented comments about the toxicity of silver nitrate to humans, particularly from the ingestion of drinking water contaminated with silver nitrate. Both respondents also expressed concern about the toxic effect on the environment through the release of silver nitrate contaminated wastes. One commentor noted that silver nitrate has been designated as a hazardous substance under both the Clean Water Act and RCRA (40CFR§261.24). Further, this commentor stated that federal, state, and local regulations often limit the amount of silver nitrate that can be discharged into state waters or sewage systems. They offered the regulations of the Sewage and Waste Control Ordinance of Metropolitan Water and Reclamation District of Greater Chicago as an example, which prohibits silver nitrate discharges into sewage waters and state waters in excess of 0.1 ppm.

In response to the issues raised by these comments, the Agency presents the following:

- Classification determination.

- Hazard identification (acute toxicity, etc.).

- Drinking water contamination.

On November 23, 1998 the Biochemical Classification Committee of BPPD determined that silver nitrate is a biochemical pesticide. This determination was based first on the committee's confirmation that the regulation of the formation of ethylene gas has historically been considered a pesticidal activity and that the silver nitrate is actually inhibiting the production of ethylene, which is in turn producing the desired effect (i.e., prevention of bud drop and wilting caused by ethylene generated by the cut flowers). The committee also concluded that this action (i.e., the prevention of the generation of ethylene gas by cut flowers) is pesticidal and that the FIFRA definition of a pesticide (growth regulator (40 CFR 152.3(k)(1)) does not preclude an indirect mode of action. Moreover, the Silver RED stated that silver is a naturally occuring element which can be found as the native metal or combined with other elements in distinct mineral phases. In making their final determination, the classification committee also noted that silver nitrate natural occurance in and non-toxic mode of action, thus making it a biochemical pesticide.

The Agency is aware of the issues relating to drinking water contamination from pesticides. The RED for Silver and Silver Compounds issued in 1993 specifically prohibited the application and discharge of compounds containing silver in marine/estuarine environments or oil fields in order to protect groundwater. The proposed uses of this silver nitrate product are indoor and greenhouse types of use. While the registrant, Pokon Chrysal BV, did not submit data concerning ecological and environmental effects, the Agency feels that these issues are adequately addressed via the precautionary labeling statements required by the RED for silver and silver compounds.

"This pesticide (product) is toxic to fish and aquatic organisms."

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permiting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product in to sewer systems without previously notifying the local sewage treatment plant authorities. For guidance, contact your State Water Board or Regional Office of EPA."

Moreover, to further mitigate any inadvertent introduction of silver nitrate into the ecosystem from the proposed pesticidal uses of the *Chrysal ABV*, the product labeling includes specific disposal instructions for spent product and wastes and equipment designed to chelate silver nitrate out of spent solutions so that they can be recycled.

1. Conditional/Unconditional Registration

All data requirements are fulfilled and BPPD recommends unconditional registration of silver nitrate.

2. CODEX Harmonization

There are no CODEX harmonization considerations since there is no food use associated with this registration.

3. Non-food Registrations

There are no non-food issues at this time. The non-food uses are listed in Appendix A, Table 4.

4. Risk Mitigation

Apart from the dermal exposure and the environmental concerns addressed above, there are no significant risk mitigation issues. Risks to floral workers and arrangers are mitigated by the required precautionary statements in the product labeling. Although short term exposure to silver nitrate may stain or the darken skin and long term exposure to silver nitrate may cause argyria in humans, this effect is only cosmetic and is not harmful to health. To this end, the Agency is requiring floral workers to wear gloves made of impermeable material sufficient to cover hands, wrist and forearms.

It is also the Agency's position, that specific product labeling requirements regarding toxicity to fish and aquatic organisms and product disposal adequately mitigate potential ecological and environmental risks. Refer to IV. RISK MANAGEMENT DECISION, C. Labeling Rationale.

5. Endangered Species Statement

The Agency recognizes that the use of silver nitrate will cause no effect to endangered species because of its use pattern and low toxicity and limited exposure to non-target organisms.

C. LABELING RATIONALE

It is the Agency's position that the product labeling proposed in this document for *Chrysal ABV*, active ingredient silver nitrate, complies with the current pesticide label requirements for biochemicals at 40 CFR 156.10.

1. Human Health Hazard

a. Worker Protection Standard

This product does not come under the provisions of the Worker Protection Standards (WPS).

b. Non-worker Protection Standard.

There are no non-WPS human toxicity issues. However, the Agency notes that there is a cosmetic issue that is undesirable and easily prevented; when excessive amounts of silver are absorbed, tissues become impregnated with silver sulfites, which form a complex in elastic fibers. Large amounts of this complex under the skin will give it bluish, grey-blue, or in extreme cases a black color. This condition is called argyria. Although it is not a toxic effect, argyria is undesirable and usually permanent. To this end, the Agency is proposing the use of protective equipment (gloves made of impermeable material sufficient to cover the hands, wrist and forearm) to mitigate the occurrence of this condition.

The use directions of this product must bear the following statement:

"This product may stain exposed skin. To prevent skin staining, workers mixing solution and handling treated flowers should wear gloves made of impermeable material sufficient to cover hands, wrists and lower forearms."

c. Precautionary Labeling

The Agency has examined the toxicological data based for *Chrysal ABV* and silver and it's compounds and concluded that the proposed precautionary labeling (i.e., Signal Word, First Aid Statement, Environmental Hazards, Disposal Statements and other label statements) adequately mitigate the risks associated with the proposed uses.

End-Use Product Pesticide disposal labeling:

"Neutralization is necessary, because the residual solution contains tiny traces of silver which may not be drained off into the surface water. The neutralization should be done with the aid of the enclosed neutralization material. Use the following procedure"

1. Put the residue in a container used exclusively for this purpose

b. Add the contents of one stachet of neutralizing powder per 100 liters of residual solution and stir.

c. After this treatment leave the liquid for one day. A grey-black deposit will be formed at the bottom.

d. The water above the drain-pipe level can then be drained off. Contact federal, state, local or Tribal authorities to obtain license for disposal of this water.

e. The remainder of the water and silt may not be drained off, but must be removed to a depot for industrial waste.

End-Use Product Precautionary Labeling: "CAUTION. Harmful if shallowed. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Wear: Long-sleeved shirt and long pants. Socks, Shoes, and Gloves. Avoid contact with eyes or clothing. Wear protective eyeware."

d. **Spray Drift Hazard**

No spray drift advisory statement is necessary for this product.

2. Environmental Hazards Labeling

End-use Product Environmental Hazards Labeling: "This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or water unless in accordance with the requirements of the National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA."

3. Application Rate

The product should be mixed and applied in the following manner:

1. Mix 1 ml of solution per quart of water in a non-metallic container. The contents of the screw cap is 1.2 US fl. Oz. (35 ml).

2. Solutions should be prepared for immediate use or for daily needs.

3. Place flowers in prepared solution immediately after cutting for a minimum of 2 hours and a maximum of 72 hours. Lilies should be treated for a minimum of 4 hours and a maximum of 36 hours.

4. Solution can be used for up to one week before needing replacement.

D. LABELING

(1) Product name: **Chrysal ABV**

Active ingredient:
Silver Nitrate 2.83%
Inert Ingredients 97.17%
Total..... 100.00%

The product label shall contain the following information:

- Product Name
- Ingredient Statement
- Registration Number
- "KEEP OUT OF REACH OF CHILDREN"
- Signal Word (CAUTION)

V. ACTIONS REQUIRED BY REGISTRANTS

Reports of incidences of adverse effects to human or domestic animals under FIFRA, Section 6(a)2 and incidents of hypersensitivity under 40 CFR Part 158.690(c), guideline reference number 152-16.

VI. APPENDIX A

Table 3 - Use sites for the product

Product Name	Use Sites	Official Date Registered
Chrysal ABV	Standard spray carnations and other ethylene sensitive cut flowers: Achillea, Aconitum, Agapanthus, Alstroemeria, Anethum, Antirrhinum, Aquilegia, Asclepais, Aster, Astrantia, Brodiaea, Campanula, Celosia, Centaurea, Chelone, Crocosmia, Delphinium, Dendrobium, Dianthus, Dicentra, Doronicum, Eremurus, Euphorbia, Eustoma, Freesia, Gentiana, Gladiolus nana, Gypsopilia, Ixia, Kniphofia, Latthyrus, Lavatera, Lulium, Matthiola, Oncidium, Phlox, Physostegia, Rudbecka, Saponaria, Scabiosa, Sidalcea, Silene, Solidago, Solidaster, Symphoricarpus, Trachelium Trolliuos en Veronica..	

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

1. Product Chemistry

Silver is a naturally occurring element which can be found as the native metal or combined with other elements in distinct mineral phases. Its physical chemistry properties are widely reported in the published scientific literature. The physical and chemical characteristics of silver are detailed below:

Chemical Name:	Silver
Chemical Formula:	Ag
Molecular Weight:	107.868
Color:	Metallic
Physical State:	Solid
Odor:	None
Melting Point:	960.5° C
Boiling Point:	2000° C
Density:	10.49 g/mL at 15° C
Solubility:	Not soluble in water
Vapor Pressure:	N/A
Dissociation Constant:	N/A
Oct/Water Part. Coeff:	N/A
pH:	N/A
Stability:	Stable to sunlight and metal/metal ions

The Agency has determined through the review of available data that elemental silver per se is not isolated during the manufacturing process, nor is it used during the manufacturing process, and that the appropriate data submitted to support the manufactured products (MP) and end use products (EP) will satisfy the generic product chemistry data requirements.

2. Residue Chemistry

The nature of the residue in plants and animals is not applicable, since treated water is used solely for human consumption, and is not directly applied to plants or consumed by livestock. Adequate analytical methodology is available for the determination of silver ions in water; the most common approach is the use of atomic absorption methods. Storage stability is not an issue for silver ions in water, since analytical methods determine total silver residues.

compounds may cause mild allergic reactions such as a rash, swelling, and inflammation in sensitive people (U.S. DHHS # TP-90-24, 1990).

b. Animal Toxicology

(1) Acute Toxicity

A single oral dose of 420 mg/kg of colloidal silver did not cause any mortality in rats (Dequidt et al., 1974). This would place silver in acute oral toxicity category III. A single application of silver nitrate (3 drops of a 0.66% solution; 42 ppm silver) into the right eye of male Wistar rats resulted in silver deposits in the cornea and conjunctiva. In addition, silver deposits were scattered in the cells of the outermost part of the anterior corneal epithelium, and heavy deposits were found in Bowman's layer, reticular fibers of the corneal stroma, Descemet's membrane, and the posterior corneal epithelium. These effects were observed 45 days after treatment and were not accompanied by any other adverse effects (Rungby, 1986). The following toxicological data were obtained from acute toxicological studies with Sildate, an end-use product containing 7.5 g powdered Sildate dispersed in 250 ml distilled water.

ACUTE TOXICITY DATA WITH SILDATE

TEST	RESULT	CATEGORY
Oral LD50	LD50 > 5000 mg/kg	IV
Inhalation LC50	N/A	N/A
Dermal LD50	LD50 > 2000 mg/kg	III
Primary Eye irritation	non-irritant	IV
Primary dermal irritation	non-irritant	IV
Dermal Sensitization	Not a sensitizer	N/A

at 65 mg/kg/day (Day et al., 1976).

(3) Chronic toxicity

In a rat study, Sprague Dawley rats (number unreported) were given silver nitrate in their drinking water at concentrations of 6 mM (648 mg/L; equivalent to 65 mg/kg/day assuming a 200 g rat drinks 20 ml water/day) for only 12 weeks or 12 mM (1,296 mg/L; 130 mg/kg/day) for 4, 6, 8, 10, 12, 16, 25, or 60 weeks. A NOEL was not established (although no toxicity was observed at 65 mg/kg/day, this dose was administered for only 12 weeks). The LOEL was established at 130 mg/kg/day, based on clinical signs of poor grooming and listlessness and histology findings of silver deposits within the glomerular basement membrane of the kidneys (Walker, 1971).

The following are three related rat studies, conducted by the same investigator:

In the first study, rats were given silver nitrate in their drinking water at a concentration equivalent to 63.5 mg/kg/day for 218 days (Olcott, 1948). No toxic effects were observed, but intense silver pigmentation of many tissues was observed at necropsy, including the basement membrane of the kidneys' tubules, the portal vein and other parts of the liver, the choroid plexus of the brain, the choroid layer of the eyes, and the thyroid gland. A NOEL was established at 63.5 mg/kg/day (silver deposition in tissues was apparently not considered an adverse effect).

In the second study, 139 albino rats were given silver nitrate in their drinking water at a concentration equivalent to 63.5 mg/kg/day for up to 553 days (Olcott, 1947). Examination of their eyes at various time points showed the color changing from normal to slightly gray after 218 days (stage 1), to more gray than pink (stage 2) after 373 days, to dark/translucent (stage 3) after 447 days, and to opaque (stage 4) after 553 days. The total cumulative amount of silver consumed at these respective stages were 3.2 g, 5.7 g, 6.8 g, and 9.4 g. Histological observation of the membrane of Bruch showed a few silver granules after 218 days and complete blackening by silver deposits after 553 days. The study did not state whether silver deposition in the eye was accompanied by any vision impairment. A NOEL was nonetheless identified at 63.5 mg/kg/day.

In the third study, older rats (> 9-months old) were given

(5) Developmental Toxicity

In a post-natal study in rats, Wistar rat pups from two litters were given subcutaneous injections of silver lactate monohydrate: two pups from each litter received daily injections of 0.10, 0.20, or 0.35 mg during post-natal weeks 1, 2, or 3 to 4, respectively. The only effect reported was that hippocampal tissues from the treated pups contained significantly ($p < 0.05$) smaller pyramidal cells. The authors speculated that the findings suggest toxicity and that the hippocampus is a selective site for silver neurotoxicity (Rungby et al. , 1987).

(6) Mutagenicity

Silver was not mutagenic in several bacterial systems. Concentrations of silver nitrate from 5×10^{-6} to 1×10^{-5}% were not mutagenic in E. coli in the absence of metabolic activation (Demerec et al., 1951). The end-point was a reversion to streptomycin independence. Silver nitrate, at 0.1 μM, was not directly mutagenic in E. coli WP2 and did not influence the mutagenic effect of ultraviolt irradiation on E. coli WP2 (Rossman and Molina, 1986). Silver chloride, at 0.05 M, was not mutagenic to B. subtilis in the absence of metabolic activation (Nishioka, 1975).

(7) Metabolism

Very little absorption occurred in rats administered carrier-free radioactive silver (<1 μg; 1 μCi) by stomach tube. Approximately 99% and 0.18% of the original dose were eliminated in the feces and urine, respectively, within 4 days after dosing. Total tissue distribution amounted to 0.835% of the administered dose (Scott and Hamilton, 1950).

Radiolabeled silver nitrate was administered by oral and i.v. routes to female RF mice (0.25 μCi, oral; 0.25 to 0.26 μCi, i.v.), male Sprague-Dawley rats (0.5 μCi via either route), beagle dogs (0.6 μCi oral, 0.4 μCi, i.v.), and Macacca mulatta monkeys (0.6 μCi via either route). In all species, cumulative excretion ranged between 90 and 99% within 2 days of oral ingestion. The extent of absorption was found to be directly proportional to the transit time through the gut in these species (Furchner et al., 1966 and 1968). About 90 to 99% of the silver administered orally as (silver nitrate) to male Sprague-Dawley rats, female beagle dogs, and Macacca mulatta monkeys was eliminated in the feces; small amounts were eliminated in the urine (Furchner et al., 1968). A

been apportioned over a lifetime of 70 years. The RfD has been verified (07/18/91) by the Agency (IRIS, 09/01/92).

2. Exposure Assessment

a. Dietary Exposure

Currently, silver is neither registered for application to food or feed crops nor is it registered for use on processed commodities. The only current dietary exposure is from the use of silver as a bacteriocide for use in human drinking water systems. The swimming pool uses of silver would not be expected to be associated with any significant dietary exposure; the SMCL of 0.1 mg/L drinking water established by the Agency's Office of Water is not expected to be exceeded following typical use of filters containing silver.

b. Occupational and Residential

Occupational exposure can be expected based on the currently registered uses of this chemical. Silver, formulated as a granular, impregnated material or soluble liquid concentrate, is used as an algicide or as part of a bacteriostatic water filter in swimming pool wataer systems and human drinking watear systems. The potential for mixer/loader/applicator exposure exists for individuals handling silver solutions or silver-impregnated filter materials. Based on the application methods (specified and implied) and the formulation types, the potential for eye, inhalation, and dermal exposure to concentrated solutions or dusts for mixers, loaders and applicators exists.

Filtering media are impregnated with concentrations ranging from 0.026% a.i. to 1.05% a.i. Soluble liquid concentrates are used for treatment in swimming pools. Typical application rates are 8 fluid ounces per 10 minute interval with a maximum of 48 fluid ounces being utilized for winterizing pools. These treatments are applied through the pool skimmer basket. With ready-to-use solutions, the potential for exposusre exists for inadvertent splashes to the eye; however, silver is not readily transported across the skin. Handling of silver-impregnated filters may frsult in short-term exposure to minute quantities of silver-containing charcoal. In general, filters containing 1.05% a.i. or less are replaced one or two times per year depending upon the use rate and rated filter capacity.

Silver concentrations in water depend upon pH and chloride concentration. Maximum silver concentrations in water are expected to be less than 10 mg/L (10 ppm). Water treatments would result in less than 0.6 ppm (0.6 mg/L) silver present in pool water (0.8% a.i. used).

C. Environmental Assessment

1. Environmental Fate

Because of the available data base on silver chemistry, most standard environmental fate data requirements were waived. The environmental chemistry section presented here is based on numerous literature sources that are cited below.

a. Environmental Chemistry - Fate and Transport

Although silver occurs as native metal, it also occurs as distinct mineral phases (mostly as sulfide minerals in complex ores) from where it is mined, processed (primarily by froth flotation) and then refined (Reese, 1985). The relative abundance of silver in the earth's crust is about 0.08 ppm (Greenwood and Earnshaw, 1984).

Silver is the metal with the highest thermal and electrical conductivity (Cotton and Wilkinson, 1988; Greenwood and Earnshaw, 1984). Although silver is, in general, not prone to ordinary oxidation and is resistant to corrosion by weak acids, the presence of sulfur-containing gases in the atmosphere and of sulfide ions in waters can tarnish the surface of silver (Murr, 1975; Pourbaix, 1974; Shumilova and Zhutaeva, 1978; Zhutaeva and Shumilova, 1985). Strong, concentrated oxidizing acid solutions can dissolve silver, producing silver(I) species in solution; in alkaline solutions, silver is generally stable (Pourbaix, 1974). Silver(I) forms soluble complexes with halide anions and with cyanide (Cotton and Wilkinson, 1988; Greenwood and Earnshaw, 1984; Irgolic and Martell, 1985). Chloride and bromide ions can react with surface silver oxides to form complexes that are more soluble than the oxides (Buffle, 1990; Pourbaix, 1974).

The oxidation states of I, II and III have been identified in silver compounds, but in aqueous media the only oxidation state is silver(I) (Cotton and Wilkinson, 1988; Shumilova and Zhutaeva, 1978). The extent of oxidation (corrosion) of silver metal in aqueous environments is thus determined by the pH, the redox potential and the temperature of the media (Morel, 1983; Murr, 1975; Pourbaix, 1974; Stumm, 1992). The type and concentration of soluble silver(I) that can form in aqueous media are determined by the nature and concentration of complexing anions present in the media; formation of insoluble phases (such as silver sulfides) are also determined by the chemical characteristics of the aqueous media (Buffle, 1990; Irgolic and Martell, 1985; Morel, 1983; Stumm, 1992).

Silver(I) can readily react with sulfide ions and organic materials

of upland gamebird and/or waterfowl were required using the formulated product (due to variations in complexes formed by pure silver as the technical grade active ingredient). The risk to birds will be assessed after the data are submitted and reviewed. However, exposure to birds is expected to be low from the pesticidal uses of silver. These studies were required for labeling statements only.

(2) Aquatic Data - Freshwater Fish, Freshwater Invertebrates & Estuarine Organisms

The acute LC_{50} for freshwater fish ranges from 3.9 to 280 $\mu g/L$ (ppb). The average toxicity values were 51.4 $\mu g/L$ for Rainbow trout (Oncorhynchus mykiss), 36.25 $\mu g/L$ for Fathead minnow (Pimphales promelas) and 44.0 $\mu g/L$ overall.

The acute EC_{50} range for freshwater invertebrates ranges from 0.25 to 4500 $\mu g/L$ (ppb). The average toxicity value for Daphnia magna was 9.21 $\mu g/L$.

The acute toxicity values for marine/estuarine fish ranged from 4.7 for Summer flounder (Paralicthys dentatus) to 1400 $\mu g/L$ for the Sheepshead minnow (Cyprinodon variegatus) with an average of 494.12 $\mu g/L$.

The values for marine/estuarine invertebrates ranged from 5.8 for the Eastern oyster (Crassostrea virginica) to 250 $\mu g/L$ for the Mysid shrimp (Mysidopsis bahia) with an average of 54.6 $\mu g/L$.

These results presented above are sufficient to indicate that silver is very highly toxic to highly toxic to fish and invertebrates. No further studies with freshwater fish, freshwater invertebrates, or estuarine organisms are required for the currently proposed uses of silver. Neither chronic nor degradate testing is required for the currently proposed uses of silver.

b. Ecological Effects Risk Assessment

Based on the available acute toxicity data, silver is highly toxic to fish and aquatic invertebrates. However, silver from products used for swimming pool and human drinking water systems is discharged into the municipal wastewater effluent and treated in municipal water treatment plants and is, therefore, regulated under NPDES permits. Little exposure to fish and aquatic invertebrates is expected from these uses. The Agency does not expect unreasonable adverse effects from these uses.

The Agency has determined that all uses of products registered as of June 23, 1993 of silver are eligible for reregistration, subject to the label and use specifications of this document.

B. Regulatory Position

The following is a summary of the regulatory positions and rationales for silver. Where labeling revisions are needed, specific language is set forth in Section V of this document.

1. Tolerance Reassessment

There are no proposed or established U.S. EPA, CODEX (international), Canadian or Mexican tolerances for silver nor exemptions from the requirements of a tolerance. Therefore, there are no harmonization issues to be resolved.

The Agency announced the deletion of the 50 μg/L MCL (maximum contaminant level) for silver on January 30, 1991 (56 Fed. Reg. 3573). Instead, a SMCL (secondary maximum contaminant level) of 100 ppb (0.1 mg/l) was established by the Agency (OW) in the same Federal Register notice, based on the skin cosmetic effect called argyria.

2. Labeling Rationale

In order to remain in compliance with FIFRA, it is the Agency's position that the labeling of all registered pesticide products containing silver must comply with the Agency's current pesticide labeling requirements. The Agency has determined that the current end-use label precautions are still appropriate and are required for product reregistration. Because the swimming pool water systeam pesticide uses of silver are regulated by an NPDES permit, it is the Agency's position that label precautions must continue to include the NPDES permit required language.

Based on the submitted data, it is the Agency's position that a label statement indicating that silver is "toxic to fish and aquatic invertebrates" must be included on all registered products containing silver in order to remain in compliance with FIFRA.

V. ACTIONS REQUIRED BY REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10. All label amendments must be submitted to the Agency within 8 months from issuance of the product specific data call-in. Please follow the instructions in the Pesticide Reregistration Handbook with respect to labels and labeling.

The Agency has determined that the current label precautions are still applicable and are required for product reregistration if the product is to remain in compliance with FIFRA.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

The registrants must clarify the nature of the "soluble liquid/concentrate" used in swimming pools, due to concerns over the potential formation of water soluble or colloidal species that may be ingested by swimmers. A new Confidential Statement of Formula (CSF) must be submitted detailing the nature of the "soluble liquid/concentrate".

Ecological effects studies on one species of upland gamebird and/or water fowl as required in the September 1992 DCI are due to the Agency shortly. Both tests are being conducted using the formulated product (due to variations in complexes formed by pure silver as the technical grade active ingredient). The risk to birds will be assessed after the data are submitted and reviewed. However, exposure to birds from the pesticide uses of silver is expected to be low. These data were required for labeling statements only.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix G; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Specifications for End-Use Products

In order to remain in compliance with FIFRA, it is the Agency's position that the following statement must be included on all products whose use requires an NPDES permit:

In order to remain in compliance with FIFRA, the labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10. All label amendments must be submitted to the Agency within 8 months from issuance of the product specific data call-in. Please follow the instructions in the Pesticide Reregistration Handbook with respect to labels and labeling.

The Agency has determined that the current label precautions are still applicable and are required for product reregistration if the product is to remain in compliance with FIFRA.

check 93-11 Sup. G

Bx1 P.E

COMFORT ZONE ®

EFFECTIVE MANAGEMENT OF NUISANCE FLIES OF HORSES
IN MANURE, STABLES, HORSE BARNS, PADDOCKS AND HORSE TRAILERS

CONTROLS FLY POPULATIONS
MAKES BEDDING UNSUITABLE FOR FLY LARVAE
CONTROLS AMMONIA ODOR IN PADDOCKS AND MANURE PILES

ACTIVE INGREDIENT	
Sodium Bisulfate [CAS# 7681-38-1]	93.2%
OTHER INGREDIENTS.....	6.8%
Total	100.0 %

KEEP OUT OF REACH OF CHILDREN

DANGER

CAUSES EYE & SKIN DAMAGE
HARMFUL IF SWALLOWED

READ BACK PANEL PRECAUTIONARY STATEMENTS CAREFULLY

READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

Manufactured by Jones-Hamilton Co.
Walbridge, OH 43465

EPA Registration No. 33907-? EPA Establishment No. 33907-OH-1

NET CONTENTS: 50 lbs

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive, causes eye and skin damage. Do not get in eyes or on skin, or on clothing. Wear goggles, or face shield and rubber gloves when handling. Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT

Applicators and other handlers MUST wear goggles or protective eyewear, long sleeved shirts, long pants, socks, shoes and rubber gloves. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instruction for washables, use detergent and hot water. Keep and wash PPE separately form other laundry.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15 - 20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING:

- Take off contaminated clothing
- Rinse skin immediately with plenty of water for 15 - 20 minutes
- Call a poison control center or doctor for treatment advice

IF SWALLOWED:

- Call a poison control center or doctor for treatment advice
- Have person sip a glass of water if able to swallow
- Do not induce vomiting unless told to do so by a poison control center or doctor
- Do not give anything by mouth to an unconscious person.

Have the product container with you when calling a poison control center or doctor, or going for treatment. You may also contact American Association of Poison Control Centers at 1-800 -222-1222 for emergency medical treatment information.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

PHYSICAL & CHEMICAL HAZARDS

Never use with products containing chlorine. Never use or mix with other chemicals.

STORAGE AND DISPOSAL STATEMENTS

Do not contaminate water, food or feed by storage or disposal

PESTICIDE STORAGE: Store in original container in a cool, dry area.

PESTICIDE DISPOSAL: Pesticides are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Completely empty bag into application equipment.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

FOR ALL APPLICATIONS OF COMFORT ZONE® IN HORSE STALLS, PADDOCKS, TRAILERS & MANURE PILES

COMFORT ZONE® is a novel fly control product for use in stables, horse barns, horse trailers paddocks and any other enclosure for horses where manure may accumulate and become a breeding source for house flies and stable flies. The active ingredient in COMFORT ZONE® is approved by the FDA as a general purpose feed additive for animal feeds.

1]. For best results a daily application is recommended.

2]. COMFORT ZONE® can be used on **any kind of bedding material** (wood shavings, sawdust, wheat straw, etc.]

3]. Apply COMFORT ZONE® evenly throughout the stall while concentrating more of the product on the wet spots. The following rates are representative and can be used as a guide.

STALL SIZE	COMFORT ZONE®
10' x 10'	1 pound or 1⅓ cups

12' x 12'	1½ pounds or 2 cups
15' x 15'	2 lbs or 2⅔ cups

4]. For additional control, apply COMFORT ZONE® directly to manures piles and/or in paddocks at the rate of 1 pound per 100 square feet.

5]. COMFORT ZONE® will not harm rubber mats

WARRANTY

Jones-Hamilton Co., warrant that this product conforms to the chemical description on the label. Jones-Hamilton Co., neither makes nor authorizes any agent or representative to make any other warranty of fitness or of merchantability, guarantee or representation, express or implied, concerning this material. Jones-Hamilton Co.'s maximum liability for breach of this warranty shall not exceed the purchase price of this product. Buyer and user acknowledge and assume all risks and liabilities resulting from the handling, storage and use of this material. that is not Conform with. Label's direction for Use

Unacceptable

Look at other labels

COMFORT ZONE ®

EFFECTIVE MANAGEMENT OF HOUSE AND STABLE FLIES
IN MANURE, STABLES, HORSE BARNS, PADDOCKS AND HORSE TRAILERS

CONTROLS FLY POPULATIONS
MAKES BEDDING UNSUITABLE FOR FLY LARVAE
CONTROLS AMMONIA ODOR IN PADDOCKS AND MANURE PILES

Sodium bisulfate OK

ACTIVE INGREDIENT	
~~Sodium hydrogen sulfate [CAS# 7681-38-1]~~	93.2%
OTHER INGREDIENTS	6.8%

KEEP OUT OF REACH OF CHILDREN

DANGER

CAUSES EYE & SKIN DAMAGE
HARMFUL IF SWALLOWED

READ BACK PANEL PRECAUTIONARY STATEMENTS CAREFULLY

READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

Manufactured by Jones-Hamilton Co.
Walbridge, OH 43465

EPA Registration No. 33907-PE

EPA Establishment No. 33907-OH-1

NET CONTENTS: 50 lbs

50981

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Protective eyewear

DANGER

Corrosive, causes eye and skin damage. Do not get in eyes or on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15 - 20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

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- Rinse skin immediately with plenty of water for 15 - 20 minutes
- Call a poison control center or doctor for treatment advice

IF SWALLOWED:

- Call a poison control center or doctor for treatment advice
- Have person sip a glass of water if able to swallow
- Do not induce vomiting unless told to do so by a poison control center or doctor
- Do not give anything by mouth to an unconscious person.

Have the product container with you when calling a poison control center or doctor, or going for treatment You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

Personal Protective Equipment → Applicators and handlers must wear goggles or face shield, long-sleeved shirt and long pants, socks, shoes and Rubber gloves.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

PHYSICAL & CHEMICAL HAZARDS

Never use with products containing chlorine. Never use or mix with other chemicals.

non-Agricultural Use Requirement
(anywhere in the directions for use section)

STORAGE AND DISPOSAL STATEMENTS

Do not contaminate water, food or feed by storage or disposal

PESTICIDE STORAGE: Store in original container in a cool, dry area.

PESTICIDE DISPOSAL: Pesticides are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned stay out of smoke

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

FOR ALL APPLICATIONS OF COMFORT ZONE® IN HORSE STALLS, PADDOCKS, TRAILERS & MANURE PILES

COMFORT ZONE® is a novel fly control product for use in stables, horse barns, horse trailers paddocks and any other enclosure for horses where manure may accumulate and become a breeding source for house flies and stable flies. The active ingredient in COMFORT ZONE® is approved by the FDA as a general purpose feed additive for animal feeds. Not on label

1]. For best results a daily application is recommended.

2]. COMFORT ZONE® can be used on **any kind of bedding material** [wood shavings, sawdust, wheat straw, etc.]

3]. Apply COMFORT ZONE® evenly throughout the stall while concentrating more of the product on the wet spots. The following rates are representative and can be used as a guide.

STALL SIZE	COMFORT ZONE®
10' x 10'	1 pound or 1⅓ cups
12' x 12'	1½ pounds or 2 cups
15' x 15'	2 lbs or 2⅔ cups

4]. For additional control, apply COMFORT ZONE® directly to manures piles and/or in paddocks at the rate of 1 pound per 100 square feet.

5]. COMFORT ZONE® will not harm rubber mats

Subject:
Re: COMFORT ZONE
Date:
Fri, 17 Jan 2003 17:09:50 -0700
From:
jazkatz <jazkatz@qwest.net>
To:
Benmhend.Driss@epamail.epa.gov
CC:
Linda Hollis <hollis.linda@epamail.epa.gov>, reilly.sheryl@epamail.epa.gov
References:
1

TO: DRISS BENMHEND
FROM: IAIN WEATHERSTON
8 PAGES
703-308-7026

Driss:
Thanks for your e-mail. In response to this e-mail I have attached a draft label in WordPerfect format (I can send you a fax
copy also, if you wish). This new draft label incorporates some of the changes requested in your e-mail.
1] as instructed the active ingredient was changed from "sodium bisulfate" to "Sodium Bisulfate."
2] the telephone number for the American Association of Poison Control Centers, 1-800-222-1222 has been added to the
paragraph at the end of the First Aid statement.
3] I have added a paragraph entitled Personal Protective Equipment.
4] It is in the request to have a Non-Agricultural Use Requirement box including the statement "Keep unprotected persons,
animals and pest from the treated areas for 48 hours" with which we cannot comply, and we do not believe that it is required.

Please consider the following:-

A] The product can be applied with the horses in the stalls or out of the stalls, the product is used with the horses present - to have a 48 hour period prior to the return of the animals obviates the use of the product. The directions for use state "For best results daily application is recommended" To have essentially what is a 48 REI defeats the purpose of the product.

B] The Directions for Use on the label of the PTL (antimicrobial product) which is identical to Comfort Zone and also used in animal premises (poultry houses) does not contain any Non Agricultural Use Statement verbiage, nor PPE statements.

C] This product is not subject to WPS since it "is applied on an agricultural establishment in the following circumstances:
(a)
(b) on livestock or other animals or in or about animal premises. " [40 CFR 170.103(b)].

D] Label Review Manual page 8-2 The answer to the first question as applied to Comfort Zone is "no" - hence WPS does not apply to this product.

E] See page 11-8 of the Label Review Manual
"If the label you are reviewing contains only uses within the scope of the WPS, you may skip this section. If the label contains entry restrictions, notification requirements or instructions similar to WPS requirements that apply to uses NOT within the scope of the WPS (non-agricultural uses), there should be a second box on the label called "Non Agricultural Use Requirements." This box maybe placed anywhere in the Directions for Use section of the label after the Agricultural Use Requirements."
The Comfort Zone label has no entry restrictions, notification requirements or instructions similar to WPS requirements because this product is exempt from all requirements of WPS.

F] The product performance data submitted in support of this product consisted of two studies published in the American Journal of Veterinary Research. In the first study [see Volume 33907-3 page 6] it says "During treatment weeks sodium bisulfate was applied daily to the top of bedding and straw, then spread on top. Ponies were kept in the stalls 24 hours a day during the 7-day test period and stall cleaning was not done." [See now page 8 Pony Observation} Signs of cutaneous lesions or lameness were not evident during the study. Ponies ate hay spread on the floor in stall corner. Their eating habits usually resulted in spreading the hay around 25% of the stall over the soiled manure. Cutaneous muzzle lesions or signs of gastrointestinal tract dysfunction were not apparent during the study. Abnormalities of appearance, actions, or attitude of any pony were not observed during the 4 week study. In the second report [beginning on page 10 of Volume Volume 33907-3] it does not say whether or not the horses were in the stalls during application but like the first study the sodium bisulfate was applied daily (in this study for 7 days). Reported in this study (on page 11 of the submitted volume) - Horses stabled in the study stalls were observed daily for skin lesions, signs of lameness, or abnormalities of appearance, actions or attitude. Farm personnel who handled the sodium bisulfate were asked to report miscellaneous health problems and cutaneous lesions. Further (on page 12) No signs of cutaneous lesions, lameness or any other health problems were evident in horses stabled in the treated stalls during the study. Signs of cutaneous lesions or other health problems were not evident among personnel handling sodium bisulfate in the study.

Driss, since Monday is a holiday in D.C. I would be obliged if you would consider the points A] through F] above, and I will
call you on Wednesday to discuss how to deal with the issues and get the product approved.
Regards,
Iain

Iain Weatherston, Ph.D.
Technology Sciences Group Inc.
4061 North 156th Drive
Goodyear, AZ 85338

Tel: 623-535-4060
Fax: 623-535-4061
E-mail: jazkatz@qwest.net

Benmhend.Driss@epamail.epa.gov wrote:

Iain:
There are few changes that must be done on label to complete my review. Please make the changes listed below and send me a revised label via e-mail (PDF file) or by mail or fax.

Page 1. Active ingredient name change to: Sodium Bisulfate
Page 2.
A. You must the 800 number for the national poison control at the end of the Fist Aid Statement
B. Add a paragraph entitled: Personal Protective Equipment:
Applicators and handlers MUST wear goggles or protective eyewear, long sleeved shirt, long pants, socks shoes and rubber gloves
Page 3.
A. Under Directions For Use, Add the " Non-Agricultural Use Requirement" box (see page 11-21 of the Label Review Manual for the appropriate language). In this box you must add: Keep unprotected persons, animals and pets from treated areas for 48 hours after treatment

Please fax or e-mail me a revised label before you print final labels.
Thanks

Driss Benmhend
United States Environmental Protection Agency
Biopesticides and Pollution Prevention Division
Biochemical Pesticides Branch
(703) 308-9525
E-mail: benmhend.driss@epa.gov

CZLABEL2.wpd

Name:
CZLABEL2.wpd

Type:
WordPerfect (application/wordperfect6.0/6.1)
Encoding:
base64

DP BARCODE: D273401

CASE: 070049 DATA PACKAGE RECORD DATE: 03/14/01
SUBMISSION: S592783 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 160 NEW PROD-"ME TOO"
CHEMICALS: 073201 Sodium bisulfate 93.2000%

ID#: 033907-E Comfort Zone
COMPANY: 033907 JONES HAMILTON CO
PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL
PM TEAM REVIEWER: DRISS BENMHEND 703-308-9525 ROOM: CS1 5TH FL
RECEIVED DATE: 01/10/01 DUE OUT DATE: 04/10/01

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 273401 EXPEDITE: N DATE SENT: 03/14/01 DATE RET.: / /
CHEMICAL: 073201 Sodium bisulfate
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 04/28/01
DIV : BPPD	/ /	/ /	NEGOT DATE: / /
BRAN: BPPD-IO	/ /	/ /	PROJ DATE: / /
SECT: IO	/ /	/ /	
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

The following data was submitted to support the me-too registration of the product "Comfort Zone":

1. Product Chemistry MRID # 453018-01
2. Product Performance MRID# 453018-02
3. Sodium bisulfate a white paper MRID # 453018-03
4. Request for waivers

Please review and comment

Thanks

Driss

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

DP BARCODE: D282440

CASE: 070049 DATA PACKAGE RECORD DATE: 07/02/02
SUBMISSION: S613533 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 161 RESB NEW PROD-"ME TOO"
CHEMICALS: 073201 Sodium bisulfate 93.2000%

ID#: 033907-E Comfort Zone
COMPANY: 033907 JONES-HAMILTON CO
PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL
PM TEAM REVIEWER: DRISS BENMHEND 703-308-9525 ROOM: CS1 5TH FL
RECEIVED DATE: 03/05/02 DUE OUT DATE: 06/03/02

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 282440 EXPEDITE: N DATE SENT: 04/17/02 DATE RET.: / /
CHEMICAL: 073201 Sodium bisulfate
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 06/01/02
DIV : BPPD	/ /	/ /	NEGOT DATE: / /
BRAN: BPPD-IO	/ /	/ /	PROJ DATE: / /
SECT: IO	/ /	/ /	
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

Attached, you will find a response to our letter (dated 9/10/01) and review (dated 8/29/01) of the data submitted to support the registration of Comfort Zone.

This package contains:

1. Letter Response
2. Administrative materials
3. Supplemental Product Chemistry MRID # 455160-01
4. Request for Waivers
5. Litterature: Response of the House Fly to Amonia and Other Substances.

Please review and comment
Thanks

Driss

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

Technology Sciences Group Inc.
Arizona: Regulatory Division
4061 North 156th Drive
Goodyear, AZ 85338
Phone: (623) 535-4060
FAX (623) 535-4061
E-Mail: jazkatz@uswest.net

Iain Weatherston, Ph.D.
Senior Regulatory Consultant
Pesticide Division

June 10, 2002

Driss Benmhend
Biochemicals Branch
Biopesticide and Pollution Prevention Division
U.S. Environmental Protection Agency
Crystal Mall #2. 9th Floor
1921 Jefferson Davis Highway
Arlington, VA 22202.

Submission dtd. 2/27/02
Sent to review 4/17/02

SUBJECT: Lack of responses to request for status of registration application.

COMPANY: Jones-Hamilton Company
30354 Tracy Road
Walbridge, Ohio 43465-9792

CONTACT: Iain Weatherston, Ph.D.
Technology Sciences Group Inc.
4061 North 156th Drive
Goodyear, Az 85338
Tel: 623-535-4060
Fax: 623-535-4061
E-mail: jazkatz@qwest.net

PRODUCT: COMFORT ZONE [33907-E]

Dear Mr. Benmhend:
As agent for, and on behalf of the Jones Hamilton Company I again write requesting a response to previous correspondence [e-mails of March 31, 2002 and May 9, 2002] regarding the status of the registration application identified above.

I note that there was an error in my e-mail of March 31 regarding chronology, I would like to correct the error at this time.

The correct chronology of this application is:

Application for registration of Comfort Zone filed:	January 8, 2001
86-5 analysis - full compliance sent out	January 19, 2001
Insufficiency letter sent by Agency	September 10, 2001
Response to September 10 letter filed	October 9, 2001
Letter from Sheryl Reilly dated November 9, 2001, detailing 86-5 rejection of a "study."	November 9, 2001
Rebuttal of this "study" rejection sent by e-mail	November 27, 2001
Inquiry about the status of "study" rejection issue sent by e-mail	December 24, 2001
Conversation with Linda Hollis at a meeting in BPPD in which she indicated that the rebuttal of the "study" rejection could not be made by e-mail and that a proper submission must be made.	February 12, 2002
Proper response to November 9, 2001 86-5 rejection filed	February 27, 2002
Request for a status of the application	March 31, 2002
Further request for status of the application	May 9, 2002

All of the deficiencies noted in the Agency's September 10, 2001 letter were addressed in the three volume

Technology Sciences Group Inc.
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Iain Weatherston, Ph.D.
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June 10, 2002

Driss Benmhend
Biochemicals Branch
Biopesticide and Pollution Prevention Division
U.S. Environmental Protection Agency
Crystal Mall #2. 9th Floor
1921 Jefferson Davis Highway
Arlington, VA 22202.

SUBJECT: Lack of responses to request for status of registration application.

COMPANY: Jones-Hamilton Company
30354 Tracy Road
Walbridge, Ohio 43465-9792

CONTACT: Iain Weatherston, Ph.D.
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Tel: 623-535-4060
Fax: 623-535-4061
E-mail: jazkatz@qwest.net

PRODUCT: COMFORT ZONE [33907-E]

Dear Mr. Benmhend:
As agent for, and on behalf of the Jones Hamilton Company I again write requesting a response to previous correspondence [e-mails of March 31, 2002 and May 9, 2002] regarding the status of the registration application identified above.

I note that there was an error in my e-mail of March 31 regarding chronology, I would like to correct the error at this time.

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Further request for status of the application	May 9, 2002

All of the deficiencies noted in the Agency's September 10, 2001 letter were addressed in the three volume

response submitted on October 8, 2001 and it is now eight months later and the Agency has not made a decision to approve the product registration nor have they seen fit to furnish a status report despite there having been two requests made.

The registrant, Jones-Hamilton Company is very unhappy that the requests for a status report have gone unanswered and have asked that I bring the matter to the attention of the Division Director and request a meeting. At this time I would prefer to seek resolution of these issues within the Branch and to that end I would request an explanation of why the product registration has not yet been approved.

Sincerely yours,

Iain Weatherston

cc: Bernie Murphy [Jones Hamilton Company]
Karl Knueven [Jones Hamilton Company]
Linda Hollis [EPA/BPPD/BB]
Ed Johnson [TSG]

Iain Weatherston
<jazkatz@uswest.net
>

11/27/2001 08:13 PM
Please respond to
jazkatz

To: Sheryl Reilly/DC/USEPA/US@EPA
cc: Driss Benmhend/DC/USEPA/US@EPA, Carl Knueven
<cknueven@jones-hamilton.com>
Subject: 86-5 COMPLIANCE LETTER DATED NOVEMBER 9, 2001

Pending Application EPA #33907-E dated October 5, 2001
Application to register COMFORT ZONE - Response to Agency letter dated September 10, 2001

Dear Sheryl:
I have just received the subject letter indicating that the Administrative volume of the submission in response to a letter from the agency is not in compliance with PRN 86-5.
This letter indicates that
Study 01 is rejected because

> no title page was included in the study, and then the letter goes on to say that one of two data confidentiality claims must be made
> the second reason given is that fewer than the required three copies of the data were submitted.

First of all the volume was not a study, it is an administrative volume and as such only one copy is required.
Second ,the volume contains, as prescribed on page 2 a perfectly correct Confidentiality Statement.

This was a submission in response to an Agency letter and the administrative volume contained correspondence, an application, a label and a confidential statement of formula. As part of the correspondence the possible modes of action of the sodium bisulfate were discussed. Rather than give merely citations I appended as attachments to the letter , and for the convenience of the reviewer, copies of literature publications going back to 1916. Explanation of the mode of action is not a requirement nor prerequisite to registration, and the submitted publications were not addressing a requirement.

I believe that there has been a misunderstanding as to the nature of Volume 33907-6 and I request that you re-examine this volume and will hopefully concur that the volume is in compliance with 86-5.
I thank you for your assistance with this matter.
Regards
Iain

Iain Weatherston
Technology Sciences Group Inc.
4061 North 156th Drive
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Tel: 623-535-4060
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Iain Weatherston, Ph.D.
Senior Regulatory Consultant
Pesticide Division

455160-00

October 5, 2001

Driss Benmhend
Biochemicals Branch
Biopesticide and Pollution Prevention Division
U. S. Environmental Protection Agency
Crystal Mall #2, 9th Floor
1921 Jefferson Davis Highway
Arlington, VA 22202

SUBJECT: Response to Agency letter dated September 10, 2001 regarding deficiencies in the application to register Comfort Zone® a novel fly control product.

COMPANY: Jones-Hamilton Company
30354 Tracy Road
Walbridge, OH 43465-9792

CONTACT: Iain Weatherston, Ph.D.
Technology Sciences Group Inc.
4061 North 156th Drive
Goodyear, AZ 85338
Tel: 623-535-4060
Fax: 623-535-4061
E-mail: jazkatz@qwest.net

Dear Driss:

As agent for, and on behalf of Jones-Hamilton Company, I submit this response to the Agency letter dated September 10, 2001 addressing the deficiencies.

All chemistry deficiencies are addressed in a separate volume as are the waiver requests. All other deficiencies are addressed in this letter. An application for pesticide registration [EPA FORM 8570-1] an updated draft label and a corrected Confidential Statement of Formula are included in this volume.

Addressing item 9 c of the DER
A waiver for the acute oral toxicity is submitted.

Addressing item 10 b of the DER
A waiver for the non-target insect study is submitted.

Addressing items 12 b and c of the DER
Regarding 12 c, in the absence of data identifying the flies adhering to the sticky tapes the claim on the label is changed to "nuisance flies of horses" as the reviewer suggested.
Regarding 12 b, the publications submitted in support of product performance show that the use of sodium bisulfate in the manner described [1] reduced ammonia in the barn environment from a range of 2 - 22.5 ppm to 0.0 - 0.75 ppm ; [2] the pH of the manure was reduced from the range 7.9 - 9.3 to 1.4 - 2.0 and [3] significantly reduces the number of flies in treated stall over untreated stalls. Since

Manufacturing process information may be entitled to confidential treatment

this effect is manifested within on the first day of treatment and continues throughout the week it is as the authors state "likely that the effect on pH or ammonia concentration is responsible for the stalls' decreased appeal to flies.

The claims on the product label are Controls fly populations, Makes bedding unsuitable for fly larvae, and Controls ammonia odor in paddocks and manure piles and the publications submitted support these claims.

The reviewer is correct in as much as a " mode of action" has not been identified however more than one mode of action may be operating.. Development of filth fly populations is dependent on several factors including [1] the ability of gravid females to find a suitable oviposition site, and [2] a suitable environment for eggs to hatch and support the development of the fly larvae. Any treatment that would mitigate against finding a site or laying the eggs, the hatching of the eggs and the subsequent development of the flies would effect a control over the fly population. [redacted] may impact one, two or more of these stages. It has been known from about 1916 that house flies [particularly female flies] are attracted to ammonia [C.H. Richardson. *The response of house flies to ammonia and other substances*. N.J. Agric. Exp. Sta. Bull. 292], other amines and putrification products such as skatole, putrescine etc. [see for example A.W.A. Brown *et al*., J. Econ Entomology 1961, 54: 670-674] and products of protein degradation. Certainly, the complexing of the sodium bisulfate with the ammonia not only reduces the odor of ammonia to mammals but is also an efficient way of reducing the semiochemical effect of the ammonia and reduce egg laying. Dr. Charles Pitts, Emeritus Professor of Entomology at Pennsylvania State University has indicated that the development of fly larvae is dependent on the temperature and pH on the manure, and that manure of pH=2 is considered toxic to fly larvae and prevents development. Work by Meyer *et al.*, and MacCreary and Haenlein, while not addressing the toxicity of very acidic manure to fly larvae does illustrate that manure pH does impact fly development. Copies of the four publications mentioned above are attached to this letter.

Jones-Hamilton believes that all outstanding deficiencies have been addressed and that the registration of Comfort Zone® should now proceed. If you have any questions or require further information, please do not hesitate to contact me by phone or e-mail.

Sincerely yours,

Iain Weatherston

attachments:

Richardson, C.H. - cited publication
Brown, A.W.A. *et al.*, - cited publication
Meyer, J. A. *et al.*, - cited publication
MacCreary and Haenlein - cited publication

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Arizona: Regulatory Division
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E-Mail: jazkatz@uswest.net

Iain Weatherston, Ph.D.
Senior Regulatory Consultant
Pesticide Division

455160-00

TECHNOLOGY SCIENCES GROUP INC

Driss Benmhend
Biochemicals Branch
Biopesticide and Pollution Prevention Division
U. S. Environmental Protection Agency
Crystal Mall #2, 9th Floor
1921 Jefferson Davis Highway
Arlington, VA 22202

October 5, 2001

SUBJECT: Response to Agency letter dated September 10, 2001 regarding deficiencies in the application to register Comfort Zone® a novel fly control product.

COMPANY: Jones-Hamilton Company
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CONTACT: Iain Weatherston, Ph.D.
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Sincerely yours,

Iain Weatherston

attachments:

Richardson, C.H. - cited publication
Brown, A.W.A. *et al.*, - cited publication
Meyer, J. A. *et al.*, - cited publication
MacCreary and Haenlein - cited publication

CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC) REQUEST FORM*

CR#: 0-0067

REQUESTOR NAME: Trauvello BeTheA REQUEST DATE: 2/6/01
TEL.:(703) 308-8714 ORG.: OPP/OPPTS/BPPD (DIV./BR./SEC.) ROOM: 910 MAIL CODE: 7511C

CSF ATTACHED:
- ☐ YES If CSF is attached complete Item A and the chemical name in Item B.
- ☐ NO If CSF is not attached complete Items A through C.

A. INFORMATION REQUIRED:

✓Check Applicable Category
- ☐ Provide PCC and Tolerance Exemption Status For Food-Use Inert Ingredient(s)
- ☐ Provide PCC for Non-Food Use Inert Ingredient (s)
- ☒ Provide PCC for Active Ingredient(s)
- ☐ Provide PCC for Dye
- ☐ Determine if Fragrance is Acceptable for Use in Formulation
- ☐ Other (Describe): _____

B. INGREDIENT INFORMATION:

Ingredient No. 1:
Chem. Name: Sodium hydrogen sulfate
Trade Name:
CAS Reg. No.:

Ingredient No. 2:
Chem. Name:
Trade Name:
CAS Reg. No.:

Ingredient No. 3:
Chem. Name:
Trade Name:
CAS Reg. No.:

Ingredient No. 4:
Chem. Name:
Trade Name:
CAS Reg. No.:

C. PESTICIDE PRODUCT INFORMATION:

EPA Reg. No./File Symbol: 33907-E Product Name:
Registrant: Food-Use Pesticide: ☐ YES ☐ NO
Percent in Formulation (For Fragrance/Dyes only):

INFORMATION REPORTED:

Ingredient No. 1:
PCC: 073201
TOL. STATUS:
OTHER INF.:

Ingredient No. 2:
PCC:
TOL. STATUS:
OTHER INF.:

Ingredient No. 3:
PCC:
TOL. STATUS:
OTHER INF.:

Ingredient No. 4:
PCC:
TOL. STATUS:
OTHER INF.:

Completed By: LINDA FAN Date Completed: 02/08/2001

*Once completed, this form may be entitled to treatment as CBI under section 10 of FIFRA. If so, a red FIFRA CBI cover should be affixed to the request form and the document handled accordingly.

DP BARCODE: D273401

CASE: 070049 DATA PACKAGE RECORD DATE: 03/14/01
SUBMISSION: S592783 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 160 NEW PROD-"ME TOO"
CHEMICALS: 073201 Sodium bisulfate 93.2000%

ID#: 033907-E Comfort Zone
COMPANY: 033907 JONES HAMILTON CO
PRODUCT MANAGER: 90 JANET ANDERSEN 703-308-8128 ROOM: CS1 5TH FL
PM TEAM REVIEWER: DRISS BENMHEND 703-308-9525 ROOM: CS1 5TH FL
RECEIVED DATE: 01/10/01 DUE OUT DATE: 04/10/01

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 273401 EXPEDITE: N DATE SENT: 03/14/01 DATE RET.: / /
CHEMICAL: 073201 Sodium bisulfate
DP TYPE: 001
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 04/28/01
DIV : BPPD	/ /	/ /	NEGOT DATE: / /
BRAN: BPPD-IO	/ /	/ /	PROJ DATE: / /
SECT: IO	/ /	/ /	
REVR :	/ /	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

The following data was submitted to support the me-too registration of the product "Comfort Zone":

1. Product Chemistry MRID # 453018-01
2. Product Performance MRID# 453018-02
3. Sodium bisulfate a white paper MRID # 453018-03
4. Request for waivers

Please review and comment

Thanks

Driss

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

Technology Sciences Group Inc.
Arizona: Registration Division
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E-Mail: jazkatz@uswest.net

Iain Weatherston, Ph.D.
Senior Regulatory Consultant
Pesticide Division

453018-00

TECHNOLOGY SCIENCES GROUP INC

Driss Benmhend
Biopesticide and Pollution Prevention Division [7511C]
U.S. Environmental Protection Agency
Crystal Mall, Building #2, 9th Floor
1921 Jefferson Davis Highway
Arlington, VA 22202

January 2, 2001

SUBJECT: Application to register Comfort Zone,® a novel fly control product for the effective management of house and stable flies in manure, stables, horse barns, paddocks and horse trailers [EPA File Symbol 33907-?]

COMPANY: Jones-Hamilton Company
30354 Tracy Road
Walbridge, OH 43465-9792

CONTACT: Iain Weatherston, Ph.D.
Technology Sciences Group, Inc.
4061 North 156th Drive,
Goodyear, AZ 85338
Tel: 623-535-4060
Fax: 623-535-4061
E-mail: jazkatz@uswest.net or iweatherston@tsgusa.com

Dear Driss:
As agent for, and on behalf of Jones-Hamilton Company, I submit for review and approval an application to register Comfort Zone,® a novel fly control product for the effective management of house and stable flies in manure, stables, horse barns, paddocks and horse trailers.

This application is submitted following a discussion of the product at a pre-application meeting held in BPPD on June 29, 2000 to discuss the subject product and its registration requirements. During the meeting Dr. Reilly requested a copy of the Mineral Acids RED [Case 4064], this document was sent to the Agency to her attention on July 3, 2000. A memorandum of understanding detailing the pre-application meeting was sent to the Agency on July 5, 2000 and was accepted without comment [a copy is attached hereto].

This administrative volume contains:

- Application for pesticide registration [OPP Identifier 270105]
- Certification with respect to data citation
- Data matrices
- Five copies of the proposed label [one bound into this volume and four loose]
- Confidential statement of formula.

In addition the application also contains the following volumes:

33907-2	PRODUCT CHEMISTRY
33907-3	PRODUCT PERFORMANCE
33907-4	REQUEST FOR WAIVERS OF SPECIFIC DATA REQUIREMENTS
33907-5	SODIUM BISULFATE - A WHITE PAPER

Comfort Zone,® is composed solely of sodium bisulfate and hence the data requirements for the end-use product will be those of the active ingredient.

If you have any questions or require further information, please do not hesitate to contact me by phone or e-mail.

Sincerely yours,

Iain Weatherston

attachment:\ MOU of pre-application meeting dated July 5, 2000

Reprinted from the AMERICAN JOURNAL OF VETERINARY RESEARCH, Vol. 61, No. 8, Pages 910-913

Effect of daily floor treatment with sodium bisulfate on the fly population of horse stalls

Corinne R. Sweeney, DVM; Tiffany Scanlon, BS; Gail E. Russell, BS; Gary Smith, PhD; Raymond C. Boston, PhD

Objective—To determine application rate and effectiveness of sodium bisulfate to decrease the fly population in a horse barn environment.

Sample Population—12 privately owned farms in southeastern Pennsylvania.

Procedure—Application rates of sodium bisulfate were approximately 2.3 kg/stall, 1.1 kg/stall, and 0.5 kg/stall. Two or 3 stalls were treated, and 1 or 2 stalls were not treated (control stalls) at each farm. Farm personnel applied sodium bisulfate in treated stalls daily for 7 days. Fly tapes were hung from the same site in treated and control stalls. After 24 hours, the fly tape was removed, flies adhering to the sticky surface were counted and recorded, and a new fly tape was hung. This procedure was repeated daily during each of the testing periods.

Results—Following the application of 2.3 kg of sodium bisulfate/stall, the numbers of flies collected on the fly tape were significantly decreased in treated stalls, compared with control stalls during the same time periods on 9 of the 12 farms evaluated. Following the application of 1.1 kg of sodium bisulfate/stall, fly numbers were significantly decreased in treated stalls on 6 of the 9 farms evaluated. Following the application of 0.5 kg of sodium bisulfate/stall, fly numbers were significantly decreased in the treated stalls on 3 of the 4 farms evaluated.

Conclusions and Clinical Relevance—Our findings suggest that sodium bisulfate would be effective for fly control in horse barns. (*Am J Vet Res* 2000; 61:910–913)

Volatilization of ammonia has been attributed to microbial decomposition of nitrogenous compounds,[1,2] principally urea, in equine manure. Manure pH has a decisive role in ammonia volatilization[3]; ammonia release is small when manure pH is < 7.0 but substantial when pH is > 8.0. Acidification has proven to be an efficient method of reducing ammonia losses in cattle slurry.[4] Sodium bisulfate, a dry acid similar in size and consistency to coarse salt crystals, is used to reduce ammonia concentration[5] and provide an environment in which bacteria cannot grow by lowering the pH in poultry litter. Sodium bisulfate (2.3 or 4.5 kg/9.3 mm^2) applied to a horse stall environment daily decreases ammonia concentration, manure pH, and number of flies in the stall environment, compared with a control period without sodium bisulfate.[5] Flyevasive behavior patterns of ponies occupying the stalls including tail swishes, head tosses, and kicking or striking, are decreased during the period of sodium bisulfate application.[5]

Results of studies indicate that equine facilities are suitable habitats for large-scale breeding of stable flies and houseflies.[6] Mean stable fly pupae production and weight is greatest in horse manure, compared with cattle, swine, and chicken manure.[7] Flies are a nuisance to horses and people working with horses. The feeding activity of face flies induces ocular lacrimation, damages conjunctival tissues, and may expose horses to fly-borne pathogens. Flies are vectors for the parasites *Habronema* and *Onchocera* spp[8,9] and have been associated with nonspecific and eosinophilic conjunctivitis. The purpose of the study reported here was to determine application rate and effectiveness of sodium bisulfate[a] to decrease the fly population in a horse barn environment.

Materials and Methods

Farms—Twelve privately owned farms in southeastern Pennsylvania were used for test sites. The farms were chosen on the basis of their accessibility and the willingness of farm personnel to record data. Age of the barns ranged from 2 to 140 years (mean – SD, 52.7 – 43.5 years). Barns were built of wood, cinder block, stone, or some combination of these materials. Flooring materials in the stalls were rubber mats (n = 7), dirt (3), stone dust (1), or blacktop (1). Bedding materials were wheat straw (n = 7), sawdust (4), or wood shavings (1). Three to 5 adjacent identically sized stalls housing horses at least 12 h/d were used in the study. Stall sizes varied from farm to farm with a range of 9.3 to 13.8 m^2. Although the manure handling procedure was the same for all stalls in a barn on each farm, procedures varied among farms. Bedding material was removed completely from stalls daily on 8 farms. Four farms picked up only fresh manure daily. Concurrent fly control methods were used on 8 farms and included chemical fly spray of stalls, fly attractant lights, or fly spray on horses on occasion. Experimental protocols were reviewed and approved by the Clinical Investigation Review Committee of the Department of Clinical Studies, New Bolton Center, University of Pennsylvania.

Application—Application rates of sodium bisulfate were approximately 2.3 kg/stall, 1.1 kg/stall, and 0.5 kg/stall. At 10 sites, 2 stalls were treated, and 2 stalls were not treated (control stalls). At 1 site, 2 stalls were treated, and 1 stall was not treated (control stall). At 1 site, 3 stalls were treated, and 2 stalls were not treated (control stalls). Farm personnel applied sodium bisulfate to treated stalls daily for 7 days.

Study design—The 12-week study was performed from June 18 through September 7, 1998 and was scheduled as follows. The first day of testing was between Jun 18 and Aug 7. The mean temperature during this period was 75.2 – 4.0 F (range, 53.1 to 93.3 F). All 12 farms first evaluated the 2.3-

Received Jun 14, 1999.
Accepted Sep 14, 1999.
From the Department of Clinical Studies, School of Veterinary Medicine, New Bolton Center, University of Pennsylvania, Kennett Square, PA 19348.
Funded by the Jones-Hamilton Co, Walbridge, Ohio.

kg/stall application rate. Between 1 and 14 days following completion of the 2.3-kg/stall testing, 9 of the 12 farms began testing the 1.1 kg/stall application rate. Between 1 and 15 days following the completion of the 1.1 kg/stall testing, 4 of these 9 farms evaluated the 0.5 kg/stall application rate.

Fly evaluation—Fly tapes[b] were hung from the same sites in each treated and control stall. Sites used were the ceiling of the center, front, or rear portion of the stall. Twenty-four hours later, the fly tape was removed, flies adhering to the sticky surface were counted and recorded, and a new fly tape was hung. This procedure was repeated daily during each of the testing periods.

Signs of toxicosis—Horses stabled in the study stalls were observed daily for skin lesions, signs of lameness, or abnormalities of appearance, actions, or attitude. Farm personnel who handled the sodium bisulfate were asked to report miscellaneous health problems and cutaneous lesions.

Statistical analyses—Because the number of flies in untreated stalls (ie, the background count) was not consistently associated with fly reduction attributable to treatment, mean daily and weekly counts of flies captured in each stall were determined. Inspection and preliminary analysis of data homogeneity suggested that determination of mean counts across replications would not lead to loss of information. For each farm, mean daily and weekly counts of flies associated with treated stalls and flies associated with untreated stalls were determined. Thus, data analysis was based on a data set containing the following variables: treatment, count of flies in treated stalls and untreated stalls, and farm identification.

To examine the likelihood of the outcome of the experiment being influenced by the temporal offset of the treatment applications, we fitted a model including time period and farm to the normalized background counts. If background count changed during the experiment, changes in fly numbers in treated stalls might otherwise be erroneously attributed to efficacy of treatments.

To compare efficacy of the 0.5-, 1.1-, and 2.3-kg/stall application rates, we used a Poisson regression model in which overdispersion was accommodated.[10] Rationale for use of this model was based on an application of Poisson regression by Clayton[11] in which the capacity of a new anticonvulsant drug to assist in the control of epilepsy was modeled. Components of our model included fly count (the dependent variable), background count as the exposure rate, treatment (as 2 indicator variables, with the 0.5-kg/stall application rate as the referent level), and farm (as 11 indicator variables). Differences were considered significant at $P < 0.05$.

Results

Fly evaluation—After application of 2.3 kg of sodium bisulfate/stall, numbers of flies collected daily and weekly on the fly tape were significantly decreased in treated stalls, compared with control stalls, during the same time periods on 9 of the 12 farms evaluated (**Fig 1 and 2**). After application of 1.1 kg of sodium bisulfate/stall, numbers of flies collected on the fly tape daily and weekly were significantly decreased in treated stalls, compared with control stalls, during the same time periods on 6 of the 9 farms evaluated. After application of 0.5 kg of sodium bisulfate/stall, numbers of flies collected on the fly tape daily and weekly were significantly decreased in treated stalls, compared with control stalls, during the same time periods on 3 of the 4 farms evaluated.

Changes in background count were not significantly associated with time of experiment. Fly numbers in any

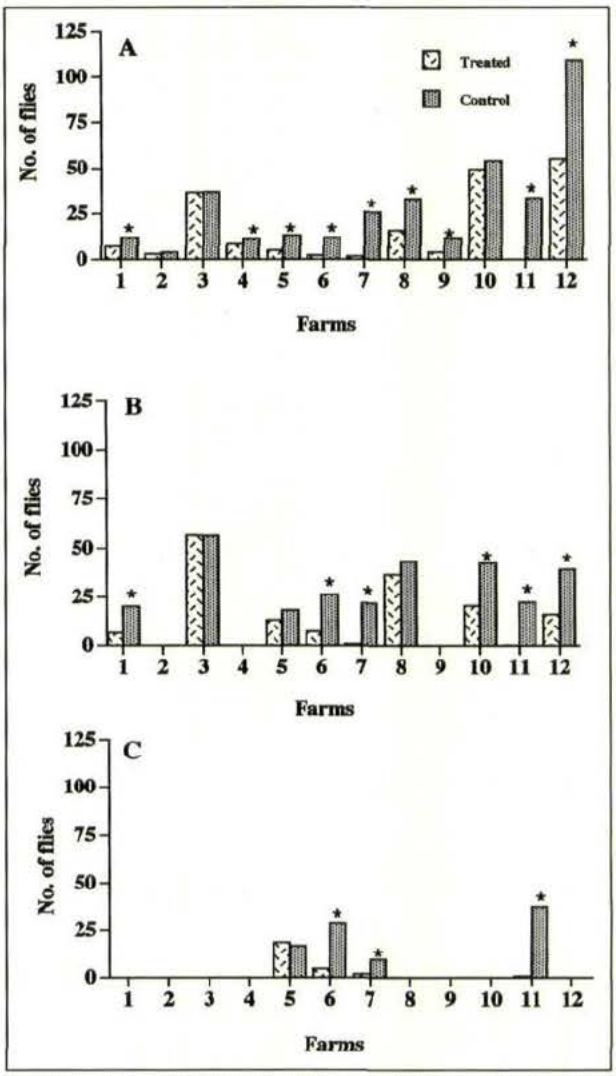

Figure 1—Mean daily fly counts in stalls treated with 2.3 kg (A), 1.1 kg (B), or 0.5 kg (C) of sodium bisulfate and untreated (control) stalls on 12 horse farms. *Significant ($P < 0.05$) difference between groups.

individual stall, either treated or control, were similar regardless of day of treatment. Magnitude of decrease in fly numbers in treated stalls was not different between the 2.3- and 1.1-kg/stall application rates. Decrease in fly numbers in the 0.5-kg treated stalls was significantly less than that in the 2.3-kg and 1.1-kg treated stalls.

The overall model was significant ($P = 0.01$), and the admission of over-dispersion was judged to be warranted ($P = 0.01$). Dispersion of the final model was approximately 0.4. Incidence rate ratios for the 1.1- and 2.3-kg application rates, compared with the 0.5-kg rate, were significantly lowered (ie, reduction in fly count for the 1.1- and 2.3-kg rates was significant, compared with the 0.5-kg rate). The incidence rate ratio for 1.1-kg rate versus the 0.5-kg rate was 0.61 − 0.10 and for the 2.3-kg rate versus the 0.5-kg rate was 0.60 − 0.10. A difference between effects of the 1.1-kg and 2.3-kg application rates was not detected. In a practical sense, this means that approximately 40% fewer flies per day were in the 1.1- and 2.3-kg treated stalls than in the 0.5-kg treated stalls. The incidence rate ratio for 0.5-kg appli-

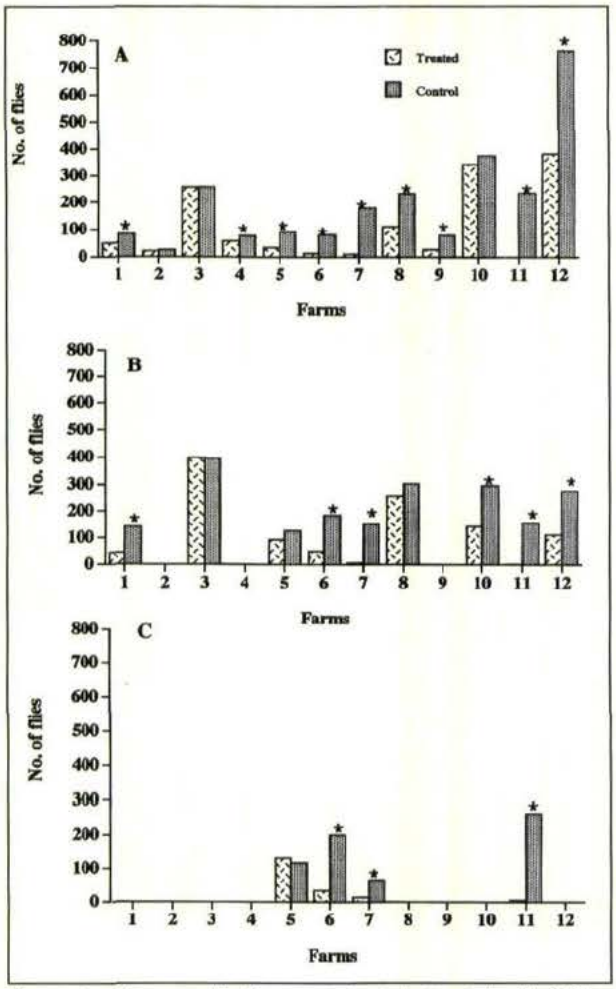

Figure 2—Mean weekly fly counts in stalls treated with 2.3 kg (A), 1.1 kg (B), or 0.5 kg (C) of sodium bisulfate and untreated (control) stalls on 12 horse farms. *Significant ($P < 0.05$) difference between groups.

cation rate versus background count was 0.21; that is, application of 0.5 kg sodium bisulfate suppressed fly counts by approximately 79%.

Different patterns of response amongst the farms was also detected. Three farms (No. 6, 7, and 11) sustained the best fly control with incidence rate ratios ranging from 0.02 to 0.40, compared with the reference farm (No. 1). Six farms (No. 2, 4, 5, 8, 9, 10, and 12) achieved approximately the same level of control as the reference farm, and 1 farm (No. 3) sustained the lowest level of fly control, with incidence rate ratios 3 times higher than those of the reference farm.

Signs of toxicosis—No signs of cutaneous lesions, lameness, or any other health problems were evident in horses stabled in the treated stalls during the study. Signs of cutaneous lesions or other health problems were not evident among personnel handling the sodium bisulfate during the study.

Discussion

The study reported here was designed so that each barn served as its own control, preventing differences in barn setting, floor or bedding material, and stall cleaning procedures from influencing evaluation of the effect of sodium bisulfate. Pairing treated and control stalls and evaluating them during the same time period eliminated the effect of season and weather on the fly population, because the control period and treated period were concurrent.

Many methods are used to monitor fly populations in the environment, including sticky fly tape, spot card, baited jug trap, grill count, and subjective visual index.[12] Sticky tape provides a simple quantitative method to monitor flies in a horse barn environment and is commonly used in commercial and recreational horse barns to control flies. Sticky fly tape was effective in a previous study[5] that monitored fly counts in horse stalls. Our study did not determine the types of flies attracted to the sticky fly tape.

Development of housefly larvae is dependent on manure pH and temperature; manure pH 2 is considered toxic to housefly larvae and prevents their development.[c] Sodium bisulfate decreases manure pH and likely prevented flies from hatching in manure in the stalls of our study. Larval development time at an environmental temperature of 35 C (95 F) or 20 C (68 F) ranges from 9 to 22 days or 6 to 8 days, respectively.[13] Although the decrease in fly numbers during the period of treatment may have been attributable to decreased larval development secondary to low manure pH, this theory would not account for the decreased fly numbers detected in treated stalls within 24 hours of application of sodium bisulfate. The authors speculate that the change in manure pH made the manure less attractive as a breeding site to adult flies already in the area.

The explanation for sodium bisulfate's lack of effectiveness in reducing fly numbers on certain farms using a particular application rate was not readily apparent. Mean weekly fly counts and mean daily fly counts in control stalls on these farms ranged from 26.5 to 765 and 3.8 to 109.3, respectively.

The effect of sodium bisulfate in decreasing fly counts in treated stalls was detectable on the first day of treatment and persisted at the same level throughout the week, suggesting that the change in the environment made the stalls immediately less appealing to the flies. A previous study[5] has documented the effect of sodium bisulfate on lowering the pH of horse manure and decreasing ammonia concentrations in stalls. It seems likely that the effect on pH or ammonia concentration is responsible for the stalls' decreased appeal to flies. Although it may be recommended that application be performed daily or every other day, the immediate effect detected in the study reported here suggests that treatment may be used as needed, because cumulative effect is not necessary to achieve decreased fly counts.

Results indicated that the highest application rate (2.3 kg/stall) had no advantage over the moderate application rate (1.1 kg/stall). Although results did suggest that the decrease in fly counts was not as great with the lowest application rate (0.5 kg/stall), sodium bisulfate remained effective on 3 of the 4 farms in which stalls were treated with that chemical concentration. To have the greatest effect, an application rate

of 1.1 kg/stall is recommended, although application at 0.5 kg/stall remains effective. The authors recommend that application be performed initially on a daily basis and continued as needed.

At no time during the study were there indications of adverse effects in horses stabled in treated stalls or farm personnel handling the sodium bisulfate. Safety issues were not expected, because sodium bisulfate is accepted as safe and can be used in food.[d]

[a]ComfortZone, Jones-Hamilton Co, Walbridge, Ohio.
[b]TAT fly paper, Walco-Linck Co, Valley Cottage, NY.
[c]Pitts C, Pennsylvania State University, Philadelphia, Penn: Personal communication, 1995.
[d]Food Chemical Codex, 4th ed, 1997, Washington, DC: National Academy Press.

References

1. Burnett WE, Dondero NC. Microbiological and chemical changes in poultry manure associated with decomposition and odor generation, in *Proceedings*. Cornell University Conf Agricultural Waste Manage 1969;271–291.
2. Carlile F. Ammonia in poultry houses: a literature review. *Worlds Poult Sci J* 1984;40:99–113.
3. Ivos J, Asaj A, Marjanovic LJ, et al. A contribution to the hygiene of deep litter in the chicken house. *Poult Sci* 1966;45:676–683.
4. Bussink DW, Huijsmans JFM, Ketelaars JJMH. Ammonia volatilization from nitric-treated cattle slurry surface applied to grassland. *Neth J Agric Sci* 1994;42:293–309.
5. Sweeney CR, McDonnell S, Russell G, et al. Effect of sodium bisulfate on ammonia concentration, fly population, and manure pH in a horse barn. *Am J Vet Res* 1996;57:1795–1798.
6. Hogsette JA. Fly control by composting manure at a south Florida equine facility. In: Patterson RS, Koehler PG, Morgan PB, et al, eds. *Status of biological control of filth flies*. Washington, DC: US Government Printing Office, 1981;105–113.
7. Boire S, Bay DE, Olson JK. An evaluation of various types of manure and vegetative material as larval breeding media for the stable fly. *Southwest Entomol* 1988;13:247–249.
8. English RV, Nasisse MP. Ocular parasites. In: Smith BP, ed. *Large animal internal medicine*. St Louis: CV Mosby Co, 1990;1245–1246.
9. Barnett KC, Crispin SM, Lavach JD, et al. *Equine color atlas and text of equine ophthalmology*. London: Mosby-Wolfe, 1995;90.
10. Lindsey JK. *Modeling frequency and count data*. Oxford, England: Clarendon Press, 1997;156–158.
11. Clayton D. Poisson regression with a random effect. In: *Stata technical bulletin*. College Station, Tex: Stata Corp, 1998: 30–33.
12. Turner EC, Ruszler PL. A quick and simple quantitative method to monitor house fly population in caged layer houses. *Poult Sci* 1989;68:833–835.
13. Axtell RC. *Fly control in confined livestock and poultry production*. Greensboro, NC: Ciba-Geigy;1986:16.

OCT 18 2001

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

JONES HAMILTON CO.
8400 ENTERPRISES DRIVE
NEWARK, CA 94560

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 10/12/01. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents. If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below. These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels. The rejected studies and their deficiencies are described below.

Rejected study [01] :

* No title page was included for this study.

You must include one of the two acceptable statements of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

* You provided fewer than the required three complete copies of submitted data.

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E-Mail: jazkatz@uswest.net

Iain Weatherston, Ph.D.
Senior Regulatory Consultant
Pesticide Division

455160-00

TECHNOLOGY SCIENCES GROUP INC

Driss Benmhend
Biochemicals Branch
Biopesticide and Pollution Prevention Division
U. S. Environmental Protection Agency
Crystal Mall #2, 9th Floor
1921 Jefferson Davis Highway
Arlington, VA 22202

October 5, 2001

SUBJECT: Response to Agency letter dated September 10, 2001 regarding deficiencies in the application to register Comfort Zone® a novel fly control product.

COMPANY: Jones-Hamilton Company
30354 Tracy Road
Walbridge, OH 43465-9792

CONTACT: Iain Weatherston, Ph.D.
Technology Sciences Group Inc.
4061 North 156th Drive
Goodyear, AZ 85338
Tel: 623-535-4060
Fax: 623-535-4061
E-mail: jazkatz@qwest.net

Dear Driss:

As agent for, and on behalf of Jones-Hamilton Company, I submit this response to the Agency letter dated September 10, 2001 addressing the deficiencies.

All chemistry deficiencies are addressed in a separate volume as are the waiver requests. All other deficiencies are addressed in this letter. An application for pesticide registration [EPA FORM 8570-1] an updated draft label and a corrected Confidential Statement of Formula are included in this volume.

Addressing item 9 c of the DER
A waiver for the acute oral toxicity is submitted.

Addressing item 10 b of the DER
A waiver for the non-target insect study is submitted.

Addressing items 12 b and c of the DER
Regarding 12 c, in the absence of data identifying the flies adhering to the sticky tapes the claim on the label is changed to "nuisance flies of horses" as the reviewer suggested.
Regarding 12 b, the publications submitted in support of product performance show that the use of sodium bisulfate in the manner described [1] reduced ammonia in the barn environment from a range of 2 - 22.5 ppm to 0.0 - 0.75 ppm ; [2] the pH of the manure was reduced from the range 7.9 - 9.3 to 1.4 - 2.0 and [3] significantly reduces the number of flies in treated stall over untreated stalls. Since

 Manufacturing process information may be entitled to confidential treatment

this effect is manifested within on the first day of treatment and continues throughout the week it is as the authors state "likely that the effect on pH or ammonia concentration is responsible for the stalls' decreased appeal to flies.

The claims on the product label are Controls fly populations, Makes bedding unsuitable for fly larvae, and Controls ammonia odor in paddocks and manure piles and the publications submitted support these claims.

The reviewer is correct in as much as a " mode of action" has not been identified however more than one mode of action may be operating.. Development of filth fly populations is dependent on several factors including [1] the ability of gravid females to find a suitable oviposition site, and [2] a suitable environment for eggs to hatch and support the development of the fly larvae. Any treatment that would mitigate against finding a site or laying the eggs, the hatching of the eggs and the subsequent development of the flies would effect a control over the fly population. [redacted] may impact one, two or more of these stages. It has been known from about 1916 that house flies [particularly female flies] are attracted to ammonia [C.H. Richardson. *The response of house flies to ammonia and other substances* . N.J. Agric. Exp. Sta. Bull. 292], other amines and putrification products such as skatole, putrescine etc. [see for example A.W.A. Brown *et al* ., J. Econ Entomology 1961, 54: 670-674] and products of protein degradation. Certainly, the complexing of the sodium bisulfate with the ammonia not only reduces the odor of ammonia to mammals but is also an efficient way of reducing the semiochemical effect of the ammonia and reduce egg laying. Dr. Charles Pitts, Emeritus Professor of Entomology at Pennsylvania State University has indicated that the development of fly larvae is dependent on the temperature and pH on the manure, and that manure of pH=2 is considered toxic to fly larvae and prevents development. Work by Meyer *et al.*, and MacCreary and Haenlein, while not addressing the toxicity of very acidic manure to fly larvae does illustrate that manure pH does impact fly development. Copies of the four publications mentioned above are attached to this letter.

Jones-Hamilton believes that all outstanding deficiencies have been addressed and that the registration of Comfort Zone® should now proceed. If you have any questions or require further information, please do not hesitate to contact me by phone or e-mail.

Sincerely yours,

Iain Weatherston

attachments:

Richardson, C.H. - cited publication
Brown, A.W.A. *et al.*, - cited publication
Meyer, J. A. *et al.*, - cited publication
MacCreary and Haenlein - cited publication

33907-E

TRANSMITTAL DOCUMENT

1.] NAME AND ADDRESS OF APPLICANT

Jones-Hamilton Company
330354 Tracy Road
Walbridge OH 43465-9792

2.] REGULATORY ACTION IN SUPPORT OF WHICH THE PACKAGE IS SUBMITTED

APPLICATION TO REGISTER COMFORT ZONE®

3.] TRANSMITTAL DATE

October 9 , 2001

4.] LIST OF SUBMITTED DOCUMENTS

VOLUME 33907-6: REJ(01) RESPONSE TO AGENCY LETTER DATED SEPTEMBER 10, 2001 ADMINISTRATIVE VOLUME, CORRESPONDENCE, APPLICATION, AND LABEL

VOLUME 33907-7: 45516001 RESPONSE TO AGENCY LETTER DATED SEPTEMBER 10, 2001 SUPPLEMENTAL PRODUCT CHEMISTRY

VOLUME 33907-8: ADMIN RESPONSE TO AGENCY LETTER DATED SEPTEMBER 10, 2001 REQUEST FOR WAIVERS OF SPECIFIC DATA REQUIREMENTS

COMPANY NAME:

Jones-Hamilton Company
330354 Tracy Road
Walbridge OH 43465-9792

COMPANY AGENT:

Iain Weatherston, Ph.D.
Technology Sciences Group, Inc.
4061 North 156th Drive
Goodyear, AZ 85338
Tel: 623-535-4060
Fax: 623-535-4061
E-mail: jazkatz@uswest.net

AGENT SIGNATURE:

Iain Weatherston

October 9 , 2001
Date

Technology Sciences Group Inc.
Arizona: Regulatory Division
4061 North 156th Drive
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E-Mail: jazkatz@uswest.net

455160-00

Iain Weatherston, Ph.D.
Senior Regulatory Consultant
Pesticide Division

Driss Benmhend
Biochemicals Branch
Biopesticide and Pollution Prevention Division
U. S. Environmental Protection Agency
Crystal Mall #2, 9th Floor
1921 Jefferson Davis Highway
Arlington, VA 22202

October 5, 2001

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Sincerely yours,

Iain Weatherston

attachments:

Richardson, C.H. - cited publication
Brown, A.W.A. *et al.*, - cited publication
Meyer, J. A. *et al.*, - cited publication
MacCreary and Haenlein - cited publication

33907-E

TRANSMITTAL DOCUMENT

1.] NAME AND ADDRESS OF APPLICANT

Jones-Hamilton Company
330354 Tracy Road
Walbridge OH 43465-9792

2.] REGULATORY ACTION IN SUPPORT OF WHICH THE PACKAGE IS SUBMITTED

APPLICATION TO REGISTER COMFORT ZONE®

3.] TRANSMITTAL DATE

October 9 , 2001

4.] LIST OF SUBMITTED DOCUMENTS

VOLUME 33907-6: REJ(01) RESPONSE TO AGENCY LETTER DATED SEPTEMBER 10, 2001
ADMINISTRATIVE VOLUME, CORRESPONDENCE, APPLICATION, AND LABEL

VOLUME 33907-7: 45516001 RESPONSE TO AGENCY LETTER DATED SEPTEMBER 10, 2001
SUPPLEMENTAL PRODUCT CHEMISTRY

VOLUME 33907-8: ADMIN RESPONSE TO AGENCY LETTER DATED SEPTEMBER 10, 2001
REQUEST FOR WAIVERS OF SPECIFIC DATA REQUIREMENTS

COMPANY NAME:

Jones-Hamilton Company
330354 Tracy Road
Walbridge OH 43465-9792

COMPANY AGENT:

Iain Weatherston, Ph.D.
Technology Sciences Group, Inc.
4061 North 156th Drive
Goodyear, AZ 85338
Tel: 623-535-4060
Fax: 623-535-4061
E-mail: jazkatz@uswest.net

AGENT SIGNATURE:

Iain Weatherston — October 9 , 2001
Iain Weatherston — Date

DATE 1-11-01

FILE NUMBER 33907-E

_____ No Data - File Room "Make Ready for _____."
(FM or Individual)

__✓__ Data - File Room "Assign Jacket to Shelf"

_____ Rejected - File Room "Assign Jacket to Rejected Shelf"

FRONT END PROCESSING APPLICATION INFORMATION CHECK

DATE: 1/11/01

PM 32

EPA COMPANY NUMBER 33907-E

EPA REGISTRATION NUMBER
STATUS (For Amendments) **Active**_____ **Cancelled**_____

Not in REFS _____

"Me-Too" CITED PRODUCT STATUS **Active**_____ **Cancelled**_____

Not in REFS _____

PRAT RECORD CREATED 1/11/01

NIFT

6

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

■ Registration
☐ Amendment
☐ Other

OPP Identifier Number: 270106

Application for Pesticide - Section I

1. Company/Product Number: 33907-3E

2. EPA Product Manager: ~~DE SHERYL REILLY~~ Robert Brome 32

3. Proposed Classification: ■ None ☐ Restricted

4. Company/Product (Name): COMFORT ZONE®

PM#: 90 (BPPD)

5. Name and Address of Applicant *(Include ZIP Code)*
JONES-HAMILTON COMPANY
30354 TRACY ROAD
WALBRIDGE OH 43465-9792

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section - II

☐ Amendment - Explain below.
■ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ■ No	☐ Yes ■ No	☐ Yes ■ No	■ Metal ■ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
*rtification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: ☐ Label ■ Container

4. Size(s) Retail Container: 50 lb bag

5. Location of Label Directions: ■ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ■ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
IAIN WEATHERSTON	SENIOR REGULATORY CONSULTANT	423-535-4060

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
Iain Weatherston	SENIOR REGULATORY CONSULTANT	
4. Typed Name: IAIN WEATHERSTON	5. Date: JANUARY 6, 2001	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.
Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

1. Company/Product Number - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. EPA Product Manager - If known, fill in the name and PM number of the EPA Product Manager.
3. Proposed Classification - Specify the proposed classification of this product.
4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of Net Contents - Indicate the location of the net contents information for your product.
4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Manner in which label is affixed to product - Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "mo[illegible]" reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

1/11/01

OFFICE OF
PREVENTION, PESTICIDE AND
TOXIC SUBSTANCES

Jones-Hamilton Company
30354 Tracy Road
Walbridge, OH 43465-9792

PRODUCT NAME: Comfort Zone
COMPANY NAME: Jones-Hamilton Company
OPP INDENTIFICATION NUMBER: 270106
EPA FILE SYMBOL: 33907-E
EPA RECEIPT DATE: 01/10/01

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT:

The Office of Pesticides Programs has received your application for a new registration and it has passed an administrative screen for completeness.

Please note that this is only a notification of receipt of your application. This is only the first step in the application process, and does NOT constitute approval.

If you have any questions please contact Robert Brennis, Product Manager 32, at (703)-308-6264.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Resources & Services Division

APPLICATION TO REGISTER COMFORT ZONE

EFFECTIVE MANAGEMENT OF HOUSE AND STABLE FLIES
IN MANURE, STABLES, HORSE BARNS PADDOCKS AND HORSE TRAILERS

End Use Product
EPA File Symbol 33907-E

VOLUME 33907-1
ADMINISTRATIVE VOLUME, CORRESPONDENCE, APPLICATION AND LABEL

DATA REQUIREMENTS
40 CFR 152.50
40 CFR 156.10

AUTHOR
Iain Weatherston

DATE COMPLETED
January 6, 2001

SPONSOR
Jones-Hamilton Company
30354 Tracy Road,
Walbridge, OH 43465-9792

SUBMITTED BY
Technology Sciences Group, Inc.
4061 North 156th Drive
Goodyear, AZ 85338

CONFIDENTIALITY CLAIMS

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A),(B) or (C) has been removed to a confidential appendix and is cited by cross-reference number in the body of the text.

Company: Jones-Hamilton Company

Agent: Iain Weatherston, Ph.D.

Signature: Iain Weatherston

Title: Senior Regulatory Consultant

Date: January 6, 2001

GOOD LABORATORY PRACTICES STATEMENT

The purpose and scope of this report **DO NOT** fall under the requirement of 40 CFR 160.

CONTENTS

Technology Sciences Group Inc.
Arizona: Registration Division
4061 North 156th Drive
Goodyear, AZ 85338
Phone: (623) 535-4060
FAX (623) 535-4061
E-Mail: jazkatz@uswest.net

Iain Weatherston, Ph.D.
Senior Regulatory Consultant
Pesticide Division

Driss Benmhend
Biopesticide and Pollution Prevention Division [7511C]
U.S. Environmental Protection Agency
Crystal Mall, Building #2, 9th Floor
1921 Jefferson Davis Highway
Arlington, VA 22202

July 5, 2000

SUBJECT: Memorandum of Understanding from Pre-Application Meeting held at the Agency on June 29, 2000.

COMPANY: Jones-Hamilton Company
30354 Tracy Road
Walbridge, OH 43465-9792

CONTACT: Iain Weatherston, Ph.D.
Technology Sciences Group, Inc.
4061 North 156th Drive
Goodyear, AZ 85338
Tel: 623-535-4060
Fax: 623-535-4061
E-mail: jazkatz@uswest.net or iweatherston@tsgusa.com

Dear Driss:

As agent for, and on behalf of Jones-Hamilton, I submit for your review and comment this memorandum of understanding regarding the discussions at the recent pre-application meeting to discuss the registration requirements for "Comfort Zone" a new fly control product for use in horse stables, barns, paddocks *etc.*

The meeting took place between 2 - 3 pm on June 29, 2000 in the large conference room on the ninth floor BPPD suite. Those in attendance were:

Sheryl Reilly, Branch Chief, Biochemicals Branch, BPPD	703-308-8269
Driss Benmhend, EPA/OPP/BBPD	703-308-8525
Carl Knueven, Jones-Hamilton Company	888-858-4425
Ed Johnson, Technology Sciences Group, Inc. [Washington, D.C.]	202-828-8951
Iain Weatherston, Technology Sciences Group, Inc. [Goodyear, AZ]	623-535-4060

After introductions, Mr. Knueven gave a brief run down on Jones-Hamilton Company and the uses of sodium bisulfate. The company was founded in 1951, is headquartered in Newark, CA, is an employee owned company and has approximately 100 employees. The primary product

line is high quality hydrogen chloride and sodium bisulfate which are prepared according to the equation:

$$NaCl + H_2SO_4 - [600°F] \rightarrow NaHSO_4 + HCl$$

The annual global production of sodium bisulfate is about 100,000 tons.. Up until recently about 30% of this production went into toilet bowl cleaners. Although this use is waning there are still two products registered by the EPA which are widely used [Crystal Vanish Toilet Bowl Cleaner and Amway Fast Acting Toilet Bowl Cleaner]. Current usage of Jones-Hamilton sodium bisulfate includes:

- in swimming pools, as a pH adjuster, it is the safest product for this use in both home and institutional swimming pools.
- in the agricultural sector it has many uses such as a poultry litter treatment to reduce the amount of free ammonia in poultry houses; as a pH adjuster for use with foliar fertilizers particularly in the major crop, cotton to reduce the speed of uptake of the fertilizer and prevent plant burn; as an adjuvant to agricultural chemical sprays to prevent loss of effectiveness due to alkaline hydrolysis [widely used with glyphosate products]
- in drinking water as a pH adjuster [approved by the National Sanitation Foundation International]
- in baking products where it is used as a processing aid at levels of 0.1 to 1.0% [GRAS Notice GRN-000003].
- in animal feeds with no restrictions with FDA permitting its use at levels that "conform with good manufacturing and feeding practices."
- Others uses include in metal finishing, leather tanning, computer chip cleaning and in the pulp and paper industry

Mr. Knueven finished by indicating that Jones-Hamilton is ISO 9002 certified, and that the bisulfate product meets the specifications of the Codex Alimentarius food standards

The use of sodium bisulfate as a fly control measure was next briefly discussed and how filth flies show positive anemotaxis to odor sources containing amines including ammonia. Gravid female filth flies searching out suitable egg-laying and larval development sites orient to ammonia and other amines produced by decaying matter or in feces. The use of sodium bisulfate to complex with the ammonia or amine results in [a] the female fly not finding a suitable oviposition site, and [b] the reduction of the pH of the manure inhibiting the development of the fly larvae.

In a discussion of the requirements Weatherston indicated that he believed the product could be registered by consideration of only product chemistry, acute toxicity and perhaps product performance requirements. Dr. Reilly corrected this statement by saying the all registration requirements applicable to the specific use of the product have to be satisfied although in this case many of them could probably be satisfied through waivers, but that waivers would have to be sought. Weatherston, in regard to product chemistry and toxicology, said that the application would rely on previously submitted studies, and decisions made by the Agency in considering the reregistration of Mineral Acids including Sodium Bisulfate and, and that the submission would contain the appropriate MRID numbers. Mr. Benmhend and Dr. Reilly requested that they be sent a copy of the Mineral Acids RED, and that the submission also contain copies of the previously submitted studies and any DER's or correspondence from

other regulatory agencies [*eg.* California DPR] referencing these studies. It was agreed that this would be done.

The question of efficacy was next discussed, the background document submitted to BPPD prior to the pre-application meeting contained two peer reviewed, published studies carried out at the School of Veterinary Medicine at the University of Pennsylvania which in Weatherston's opinion satisfied the label claims made for this product and should be submitted in the application to satisfy the product performance requirements. Dr. Reilly said that BPPD were not willing to comment on these studies nor the draft label at this time, but that the studies would be reviewed by either Russ Jones or Robyn Rose and comments on their suitability passed on to Weatherston within two weeks.
The question of whether a conditional registration be sought if the efficacy studies were found not to satisfy the requirements and Jones-Hamilton had to develop a protocol for BPPD review and then carry out the study was briefly mentioned but Dr. Reilly opined that this question would be better discussed only if it subsequently proved to be appropriate.

A discussion ensued about a competitive product to Comfort Zone, this product called FlyCracker is composed of 100% citric acid and is being advertised "as completely safe to planet earth and to the humans who inhabit it." This product is exempt from FIFRA regulation since the active ingredient is classified as "a minimum risk pesticide" at 40 CFR 152.25(g). Jones-Hamilton were interested in whether Comfort Zone could be exempted from FIFRA regulation. Dr. Reilly indicated that an application could be made to place sodium bisulfate on the minimum risk pesticide list, but agreed with Weatherston, that registering the product was a more expeditious route to the market place. Dr. Reilly also commented that some "minimum risk pesticide" products can have complicated regulatory issues at the state level.

Weatherston asked if BPPD could give Jones-Hamilton an idea of the current review times for biochemical or biochemical like products; reluctantly, it was stated that possibly the review time would be 12 months "more or less."

There being no more items relating to Comfort Zone to be discussed Weatherston thanked the BPPD personnel for arranging and participating in the meeting.

ACTION ITEMS FROM THE MEETING

1] BPPD will review the efficacy studies submitted as part of the background document and provide Weatherston by July 15, 2000 with their comments in regard to their satisfying product performance guidelines.

2] Technology Sciences Group, Inc on behalf of Jones-Hamilton will provide BBPD with:

- a copy of the Mineral Acids RED [the document was sent FedEx on July 3, 2000].
- Copies of the product chemistry and toxicity studies [MRID's 41622301 and 41622302] together with any DER's or other regulatory agency reviews which they can obtain. These documents will be submitted as part of the application for registration of Comfort Zone.

Driss, this then is my recollection of the meeting and I have the concurrence of Carl Knueven and Ed Johnson. Should there be any discrepancies or omissions from either Sheryl's or your recollection of the meeting I would be obliged of you would let me know so that this record may be corrected.

Regards,

Iain Weatherston

cc: Sheryl Reilly [BPPD]
Carl Knueven [Jones-Hamilton Company]
Ed Johnson [Technology Sciences Group, Inc].

PLACE HOLDER PAGE

CROSS REFERENCE NUMBER; **[1]**

The cross reference number noted on this place holder page is used in place of the following whole page(s).

DELETED PAGE(S): Found in the Confidential Attachment

PAGE(S)	REASON FOR THE DELETION	FIFRA REFERENCE
13	Confidential Statement of Formula	§ 10(d)(1)(C)

Form Approved OMB No, 2070-0060

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401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date January 5, 2001	EPA Reg. No./File Symbol 33907-~~R~~ E	Page 1 of 3
Applicant's/Registrant Name and Address: Jones-Hamilton Company, 30354 Tracy Road, Walbridge, OH 43465-9792	Product COMFORT ZONE ®	

Ingredient Sodium bisulfate

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-10	Product identity	41622301	Sodium bisulfate joint venture in association with Jones-Hamilton	OWN	
151-10	Product identity		this submission Volume 33907-2	OWN	
151-11	Manufacturing process	41622301	Sodium bisulfate joint venture in association with Jones-Hamilton	OWN	
151-11	Manufacturing process		this submission Volume 33907-2	OWN	
151-12	Formation of unintentional ingredients	41622301	Sodium bisulfate joint venture in association with Jones-Hamilton	OWN	
151-12	Formation of unintentional ingredients		this submission Volume 33907-2	OWN	
151-13	Analysis of samples (Preliminary analysis)	41622301	Sodium bisulfate joint venture in association with Jones-Hamilton	OWN	
151-15	Certification of limits		this submission Volume 33907-2	OWN	
151-16	Analytical methods	41622301	Sodium bisulfate joint venture in association with Jones-Hamilton	OWN	
151-17	Physical/chemical properties	41622301	Sodium bisulfate joint venture in association with Jones-Hamilton	OWN	
151-17	Physical chemical properties		this submission Volume 33907-2	OWN	

Signature	Name and Title: Iain Weatherston, Senior Regulatory Consultant	Date: January 6, 2001

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DATA MATRIX

Date January 5, 2001	EPA Reg. No./File Symbol 33907-E	Page 2 of 3
Applicant's/Registrant Name and Address: Jones-Hamilton Company, 30354 Tracy Road, Walbridge, OH 43465-9792	Product COMFORT ZONE®	

Ingredient: Sodium bisulfate

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-10	Acute oral toxicity	41622302	Sodium bisulfate joint venture in association with Jones-Hamilton	OWN	
152-11	Acute dermal toxicity		this submission Volume 33907-4	Waiver	
152-12	Acute inhalation toxicity		this submission Volume 33907-4	Waiver	
152-13	Primary eye irritation		This submission Volume 33907-4	Waiver	
152-14	Primary dermal irritation	41622302	Sodium bisulfate joint venture in association with Jones-Hamilton	OWN	
152-15	Hypersensitivity study		this submission Volume 33907-4	Waiver	
152-16	Hypersensitivity incident			n/a	will be reported
152-17	Studies to detect genotoxicity		this submission Volume 33907-4	Waiver	
152-18	Immune response		this submission Volume 33907-4	Waiver	
152-19	90-day feeding			n/a	
152-20	90-day dermal			n/a	
152-21	90-day inhalation			n/a	

Signature: [redacted] Name and Title: Iain Weatherston, Senior Regulatory Consultant Date: January 6, 2001

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Applicant's/Registrant Name and Address: Jones-Hamilton Company, 30354 Tracy Road, Walbridge, OH 43465-9792	Product COMFORT ZONE®	

Ingredient: Sodium bisulfate

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-23	Teratogenicity		this submission Volume 33907-4	Waiver	
152-19	Mammalian mutagenicity tests			n/a	
152-24	Immune response			n/a	
152-26	Chronic exposure			n/a	
152-29	Oncogenicity			n/a	
154-6	Avian acute oral		this submission Volume 33907-4	Waiver	
154-7	Avian dietary		this submission Volume 33907-4	Waiver	
154-8	Freshwater fish LC50		this submission Volume 33907-4	Waiver	
154-9	Freshwater invertebrate LC50		this submission Volume 33907-4	Waiver	
95-11	Product performance		this submission Volume 33907-3	PL	

Signature: Iain Weatherston

Name and Title: Iain Weatherston, Senior Regulatory Consultant

Date: January 6, 2001

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Ingredient: Sodium bisulfate

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Sodium bisulfate joint venture in association with Jones-Hamilton	OWN	
			this submission Volume 33907-2	OWN	
			Sodium bisulfate joint venture in association with Jones-Hamilton	OWN	
			this submission Volume 33907-2	OWN	
			Sodium bisulfate joint venture in association with Jones-Hamilton	OWN	
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			Sodium bisulfate joint venture in association with Jones-Hamilton	OWN	
			this submission Volume 33907-2	OWN	
			Sodium bisulfate joint venture in association with Jones-Hamilton	OWN	
			Sodium bisulfate joint venture in association with Jones-Hamilton	OWN	
			this submission Volume 33907-2	OWN	

Signature	Name and Title: Iain Weatherston, Senior Regulatory Consultant	Date: January 8, 2001

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Date January 5, 2001	EPA Reg. No./File Symbol 33907-~~R~~ E	Page 2 of 3
Applicant's/Registrant Name and Address: Jones-Hamilton Company, 30354 Tracy Road, Walbridge, OH 43465-9792	Product COMFORT ZONE®	
Ingredient: Sodium bisulfate		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Sodium bisulfate joint venture in association with Jones-Hamilton	OWN	
			this submission Volume 33907-4	Waiver	
			this submission Volume 33907-4	Waiver	
			This submission Volume 33907-4	Waiver	
			Sodium bisulfate joint venture in association with Jones-Hamilton	OWN	
			this submission Volume 33907-4	Waiver	
				n/a	will be reported
			this submission Volume 33907-4	Waiver	
			this submission Volume 33907-4	Waiver	
				n/a	
				n/a	
				n/a	

Signature	Name and Title: Iain Weatherston, Senior Regulatory Consultant	Date: January 5, 2001

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

Agency Internal Use Copy

158

Jones-Hamilton Company - Comfort Zone - 33907-1
Page 18 of 26

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date January 5, 2001	EPA Reg. No./File Symbol 33907-~~R~~ E	Page 3 of 3
Applicant's/Registrant Name and Address: Jones-Hamilton Company, 30354 Tracy Road, Walbridge, OH 43465-9792	Product COMFORT ZONE ®	

Ingredient: Sodium bisulfate

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			this submission Volume 33907-4	Waiver	
				n/a	
				n/a	
				n/a	
				n/a	
			this submission Volume 33907-4	Waiver	
			this submission Volume 33907-4	Waiver	
			this submission Volume 33907-4	Waiver	
			this submission Volume 33907-4	Waiver	
			this submission Volume 33907-3	PL	

Signature	Name and Title: Iain Weatherston, Senior Regulatory Consultant	Date: January 6, 2001

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number: JONES-HAMILTON COMPANY 30354 TRACY ROAD, WALBRIDGE OH 43465 419-666-9838	EPA Registration Number/File Symbol: 33907-E
Active Ingredient(s) and/or representative test compound(s): SODIUM BISULFATE	Date: JANUARY 6, 2004
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158): INDOOR : PETS AND DOMESTIC ANIMALS – ANIMALS/MAN MADE PREMISES	Product Name: COMFORT ZONE®

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

■ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

■ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Ian Weatherston	JAN 6, 2004	IAN WEATHERSTON / SENIOR REGULATORY CONSULTANT

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

WARRANTY

Jones-Hamilton Co., warrant that this product conforms to the chemical description on the label. Jones-Hamilton Co., neither makes nor authorizes any agent or representative to make any other warranty of fitness or of merchantability, guarantee or representation, express or implied, concerning this material. Jones-Hamilton Co.'s maximum liability for breach of this warranty shall not exceed the purchase price of this product. Buyer and user acknowledge and assume all risks and liabilities resulting from the handling, storage and use of this material.

APPLICATION TO REGISTER COMFORT ZONE

EFFECTIVE MANAGEMENT OF HOUSE AND STABLE FLIES
IN MANURE, STABLES, HORSE BARNS PADDOCKS AND HORSE TRAILERS

End Use Product
EPA File Symbol 33907-?

VOLUME 33907-1CA
CONFIDENTIAL ATTACHMENT

DATA REQUIREMENTS
40 CFR 152.50
40 CFR 156.10

AUTHOR
Iain Weatherston

DATE COMPLETED
January 2, 2001

SPONSOR
Jones-Hamilton Company
30354 Tracy Road,
Walbridge, OH 43465-9792

SUBMITTED BY
Technology Sciences Group, Inc.
4061 North 156th Drive
Goodyear, AZ 85338

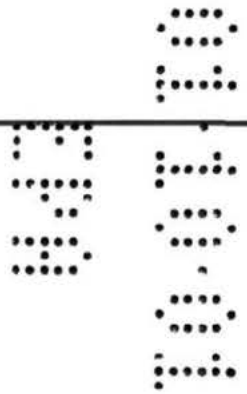
CROSS REFERENCE PAGE

CROSS REFERENCE NUMBER; [1]

The cross reference number noted on the place holder page was used in place of the following whole page(s).

DELETED PAGE(S): Found in the Confidential Attachment

PAGE(S)	REASON FOR THE DELETION	FIFRA REFERENCE
13	Confidential Statement of Formula	§ 10(d)(1)(C)



COMFORT ZONE ®

EFFECTIVE MANAGEMENT OF HOUSE AND STABLE FLIES
IN MANURE, STABLES, HORSE BARNS, PADDOCKS AND HORSE TRAILERS

CONTROLS FLY POPULATIONS
MAKES BEDDING UNSUITABLE FOR FLY LARVAE
CONTROLS AMMONIA ODOR IN PADDOCKS AND MANURE PILES

ACTIVE INGREDIENT	
Sodium hydrogen sulfate [CAS# 7681-38-1]	93.2%
OTHER INGREDIENTS	6.8%

KEEP OUT OF REACH OF CHILDREN

DANGER

CAUSES EYE & SKIN DAMAGE
HARMFUL IF SWALLOWED

READ BACK PANEL PRECAUTIONARY STATEMENTS CAREFULLY

READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

Manufactured by Jones-Hamilton Co.
Walbridge, OH 43465

EPA Registration No. 33907-~~2~~E

EPA Establishment No. 33907-OH-1

NET CONTENTS: 50 lbs

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive, causes eye and skin damage. Do not get in eyes or on skin, or on clothing. Wear goggles, or face shield and rubber gloves when handling. Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

IF IN EYES:

- ➤ Hold eye open and rinse slowly and gently with water for 15 - 20 minutes.
- ➤ Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- ➤ Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING:

- ➤ Take off contaminated clothing
- ➤ Rinse skin immediately with plenty of water for 15 - 20 minutes
- ➤ Call a poison control center or doctor for treatment advice

IF SWALLOWED:

- ➤ Call a poison control center or doctor for treatment advice
- ➤ Have person sip a glass of water if able to swallow
- ➤ Do not induce vomiting unless told to do so by a poison control center or doctor
- ➤ Do not give anything by mouth to an unconscious person.

Have the product container with you when calling a poison control center or doctor, or going for treatment You may also contact 1-800 -xxx-xxxx for emergency medical treatment information.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

PHYSICAL & CHEMICAL HAZARDS

Never use with products containing chlorine. Never use or mix with other chemicals.

STORAGE AND DISPOSAL STATEMENTS

Do not contaminate water, food or feed by storage or disposal

PESTICIDE STORAGE: Store in original container in a cool, dry area.

PESTICIDE DISPOSAL: Pesticides are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned stay out of smoke

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

FOR ALL APPLICATIONS OF COMFORT ZONE® IN HORSE STALLS, PADDOCKS, TRAILERS & MANURE PILES

COMFORT ZONE® is a novel fly control product for use in stables, horse barns, horse trailers paddocks and any other enclosure for horses where manure may accumulate and become a breeding source for house flies and stable flies. The active ingredient in COMFORT ZONE® is approved by the FDA as a general purpose feed additive for animal feeds.

1]. For best results a daily application is recommended.

2]. COMFORT ZONE® can be used on **any kind of bedding material** [wood shavings, sawdust, wheat straw, etc.]

3]. Apply COMFORT ZONE® evenly throughout the stall while concentrating more of the product on the wet spots. The following rates are representative and can be used as a guide.

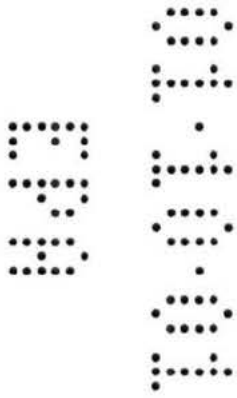
STALL SIZE	COMFORT ZONE®
10' x 10'	1 pound or 1⅓ cups
12' x 12'	1½ pounds or 2 cups
15' x 15'	2 lbs or 2⅔ cups

4]. For additional control, apply COMFORT ZONE® directly to manures piles and/or in paddocks at the rate of 1 pound per 100 square feet.

5]. COMFORT ZONE® will not harm rubber mats

WARRANTY

Jones-Hamilton Co., warrant that this product conforms to the chemical description on the label. Jones-Hamilton Co., neither makes nor authorizes any agent or representative to make any other warranty of fitness or of merchantability, guarantee or representation, express or implied, concerning this material. Jones-Hamilton Co.'s maximum liability for breach of this warranty shall not exceed the purchase price of this product. Buyer and user acknowledge and assume all risks and liabilities resulting from the handling, storage and use of this material.



COMFORT ZONE ®

EFFECTIVE MANAGEMENT OF HOUSE AND STABLE FLIES
IN MANURE, STABLES, HORSE BARNS, PADDOCKS AND HORSE TRAILERS

CONTROLS FLY POPULATIONS
MAKES BEDDING UNSUITABLE FOR FLY LARVAE
CONTROLS AMMONIA ODOR IN PADDOCKS AND MANURE PILES

ACTIVE INGREDIENT	
Sodium hydrogen sulfate [CAS# 7681-38-1]	93.2%
OTHER INGREDIENTS	6.8%

KEEP OUT OF REACH OF CHILDREN

DANGER

CAUSES EYE & SKIN DAMAGE
HARMFUL IF SWALLOWED

READ BACK PANEL PRECAUTIONARY STATEMENTS CAREFULLY

READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

Manufactured by Jones-Hamilton Co.
Walbridge, OH 43465

EPA Registration No. 33907-?

EPA Establishment No. 33907-OH-1

NET CONTENTS: 50 lbs

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive, causes eye and skin damage. Do not get in eyes or on skin, or on clothing. Wear goggles, or face shield and rubber gloves when handling. Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

IF IN EYES:

- ➤ Hold eye open and rinse slowly and gently with water for 15 - 20 minutes.
- ➤ Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- ➤ Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING:

- ➤ Take off contaminated clothing
- ➤ Rinse skin immediately with plenty of water for 15 - 20 minutes
- ➤ Call a poison control center or doctor for treatment advice

IF SWALLOWED:

- ➤ Call a poison control center or doctor for treatment advice
- ➤ Have person sip a glass of water if able to swallow
- ➤ Do not induce vomiting unless told to do so by a poison control center or doctor
- ➤ Do not give anything by mouth to an unconscious person.

Have the product container with you when calling a poison control center or doctor, or going for treatment You may also contact 1-800 -xxx-xxxx for emergency medical treatment information.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

PHYSICAL & CHEMICAL HAZARDS

Never use with products containing chlorine. Never use or mix with other chemicals.

STORAGE AND DISPOSAL STATEMENTS

Do not contaminate water, food or feed by storage or disposal

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PESTICIDE DISPOSAL:	Pesticides are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.
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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

FOR ALL APPLICATIONS OF COMFORT ZONE® IN HORSE STALLS, PADDOCKS, TRAILERS & MANURE PILES

COMFORT ZONE® is a novel fly control product for use in stables, horse barns, horse trailers paddocks and any other enclosure for horses where manure may accumulate and become a breeding source for house flies and stable flies. The active ingredient in COMFORT ZONE® is approved by the FDA as a general purpose feed additive for animal feeds.

1]. For best results a daily application is recommended.

2]. COMFORT ZONE® can be used on **any kind of bedding material** (wood shavings, sawdust, wheat straw, etc.]

3]. Apply COMFORT ZONE® evenly throughout the stall while concentrating more of the product on the wet spots. The following rates are representative and can be used as a guide.

STALL SIZE	COMFORT ZONE®
10' x 10'	1 pound or 1⅓ cups
12' x 12'	1½ pounds or 2 cups
15' x 15'	2 lbs or 2⅔ cups

4]. For additional control, apply COMFORT ZONE® directly to manures piles and/or in paddocks at the rate of 1 pound per 100 square feet.

5]. COMFORT ZONE® will not harm rubber mats

WARRANTY

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IN MANURE, STABLES, HORSE BARNS, PADDOCKS AND HORSE TRAILERS

CONTROLS FLY POPULATIONS
MAKES BEDDING UNSUITABLE FOR FLY LARVAE
CONTROLS AMMONIA ODOR IN PADDOCKS AND MANURE PILES

ACTIVE INGREDIENT	
Sodium hydrogen sulfate [CAS# 7681-38-1]	93.2%
OTHER INGREDIENTS	6.8%

KEEP OUT OF REACH OF CHILDREN

DANGER

CAUSES EYE & SKIN DAMAGE
HARMFUL IF SWALLOWED

READ BACK PANEL PRECAUTIONARY STATEMENTS CAREFULLY

READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

Manufactured by Jones-Hamilton Co.
Walbridge, OH 43465

EPA Registration No. 33907-?

EPA Establishment No. 33907-OH-1

NET CONTENTS: 50 lbs

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

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PHYSICAL & CHEMICAL HAZARDS

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STORAGE AND DISPOSAL STATEMENTS

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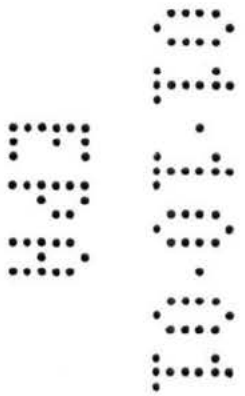

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Manufactured by Jones-Hamilton Co.
Walbridge, OH 43465

EPA Registration No. 33907-?

EPA Establishment No. 33907-OH-1

NET CONTENTS: 50 lbs

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